# THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE CENTERS FOR DISEASE CONTROL AND PREVENTION NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes

**MEETING THREE** 

WORLD TRADE CENTER HEALTH PROGRAM

SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE

WEDNESDAY, MARCH 28, 2012

**TELECONFERENCE** 

The verbatim transcript of the

Meeting of the Scientific/Technical Advisory

Committee held telephonically on March 28, 2012.

STEVEN RAY GREEN AND ASSOCIATES NATIONALLY CERTIFIED COURT REPORTERS 404/733-6070

# CONTENTS March 28, 2012

| WELCOME AND INTRODUCTION ELIZABETH WARD, PhD, CHAIR JOHN HOWARD, MD, PROGRAM ADMINISTRAT | OR  | 7  |
|--|-----|----|
| PUBLIC COMMENTS  |     | 18 |
| DISCUSSION OF CANCER PETITION<br>ELIZABETH WARD, PhD, CHAIR                              |     | 56 |
| ADMINISTRATIVE ISSUES AND ADJOURN ELIZABETH WARD, PhD, CHAIR                             | 214 |    |

### TRANSCRIPT LEGEND

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- -- (sic) denotes an incorrect usage or pronunciation of a word which is transcribed in its original form as reported.
- -- (phonetically) indicates a phonetic spelling of the word if no confirmation of the correct spelling is available.
- -- "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.
  - -- "\*" denotes a spelling based on phonetics, without reference available.
- -- (inaudible)/ (unintelligible) signifies speaker failure, usually failure to use a microphone.

## PARTICIPANTS

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| 4  | Recovery Workers:   |
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| 8<br>9<br>10               | Representative of Certified-Eligible WTC Survivors:<br>Kimberly Flynn,<br>Co-Founder, Director, 9/11 Environmental Action   |
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| 15<br>16                   | Susan Sidel, J.D.<br>Resident of New York City and volunteer WTC responder.   |
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| 21<br>22<br>23<br>24<br>25 | Toxicologist: Julia Quint, Ph.D. Research Scientist Supervisor II and Chief, Hazard Evaluation System and Information Service (HESIS), Occupational Health Branch, California Department of Public Health (retired), Oakland.   |
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| 30                         |   |

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|----|--|
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| 13 |  |
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| 16 | Paul J. Middendorf, Ph.D., CIH   |
| 17 | Senior Scientist   |
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| 20 |  |
| 21 |  |
| 22 |  |
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#### PROCEEDINGS

1 2 **WELCOME AND INTRODUCTION** 3 DR. MIDDENDORF: Okay, let's go ahead and start. Good 4 afternoon, everybody, this is Paul Middendorf. I want to extend a 5 6 THE OPERATOR: Mr. Middendorf? 7 8 phone with us. 9 THE OPERATOR: Mr. Middendorf? 10 11 12 13 THE OPERATOR: Paul? 14 DR. MIDDENDORF: Yes? 15 16 are you ready to start that recording? 17 18 **THE OPERATOR:** Okay. Give me just one second for you. Okay? 19 DR. MIDDENDORF: Yes. 20 (Pause) 21 22 23 24 25 26 27 28 29

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(1:00 p.m.)

warm welcome to the Committee members and --

**DR. MIDDENDORF:** -- the members of the public who are on the

**DR. MIDDENDORF:** We appreciate your interest in these proceedings. For those of you who have signed up to provide public comments, they are scheduled to begin at one --

THE OPERATOR: This is the operator. You have to let me know --

**DR. MIDDENDORF:** Yes, we're ready to start the recording.

**THE OPERATOR:** Thank you, sir. Your call is being recorded. **DR. MIDDENDORF:** All right. Thank you. For those of you who have signed up to provide public comments, they're scheduled to begin at 1:10 this afternoon so we'll start those in just a few minutes. I have a few administrative details I need to go over. For our public commenters who are on the phone, I just want to review some telephone conference etiquette. We do want to provide as much public access to these Committee meetings as possible, but it's very important that the Committee members be able to hear, and every member of the public who wants to hear the proceedings be able to hear also. So just to remind you that your phone should be muted until I call your name. If you don't have a mute button on your phone, theoretically you can dial star-6 to mute your phone electronically. And to unmute it you can just

repeat that, dial star-6 again. So for the public commenters, when you've finished with your comments we'll ask you to mute your phone when you're finished.

It's very important for us to remember why we're here and why we're meeting and set the appropriate tone for the meeting, so let's spend just a few moments in silence to remember those who were killed in the attacks on 9/11, and also those responders and survivors who have since died because of this.

#### (Pause)

UNIDENTIFIED: Paul, can you hear me?

**DR. MIDDENDORF:** Yes.

**UNIDENTIFIED:** I have two of your public speakers here in the room with me, T.J. and Jacques.

**DR. MIDDENDORF:** Okay. Please keep your phone on mute until we ask for them to speak.

#### (Pause)

**DR. MIDDENDORF:** Okay. Thank you. We do -- just to remind folks that copies of the agenda for this half-day telephone meeting can be found on the Committee's website. If you're logged into the live meeting or my meetings, it's the web conference part. You should also be able to see it there as well.

Copies of the public comments that were received as of March 27th around noon have been provided to the Committee before this meeting so they'd have a chance to see those. They will also be posted on NIOSH's docket 248, which is also available through the Committee's website.

I'd like to do a roll call for the committee members now. So for the roll call I'll call out the name of each member and ask you to let me know that you're on the line. I'll also ask you to state whether or not there have been any changes in your employment or interests that would affect your conflict of interest. Also remind you that if you need to leave the call, please let me know when you leave and also when you return, to be certain that we continue to have a quorum. Okay.

So Tom Aldrich?

| 1  | DR. ALDRICH: Here, and there have been no changes in my conflict |
|----|--|
| 2  | of interest statement.   |
| 3  | DR. MIDDENDORF: Okay. Steve Cassidy?                             |
| 4  | MR. CASSIDY: (No response)                                       |
| 5  | DR. MIDDENDORF: Steve?   |
| 6  | MR. CASSIDY: (No response)                                       |
| 7  | DR. MIDDENDORF: And not hearing, he's not present.               |
| 8  | Valerie Dabas?   |
| 9  | MS. DABAS: I'm here. No changes to my employment.                |
| 10 | DR. MIDDENDORF: John Dement?                                     |
| 11 | DR. DEMENT: I'm here, no changes.                                |
| 12 | DR. MIDDENDORF: Kimberly Flynn?                                  |
| 13 | MS. FLYNN: Here, and no changes.                                 |
| 14 | DR. MIDDENDORF: Bob Harrison?                                    |
| 15 | DR. HARRISON: Here, and no changes.                              |
| 16 | DR. MIDDENDORF: Catherine Hughes?                                |
| 17 | MS. HUGHES: Here, and no changes.                                |
| 18 | DR. MIDDENDORF: Steve Markowitz I don't believe is going to be   |
| 19 | on but I'll check Steve?   |
| 20 | DR. MARKOWITZ: (No response)                                     |
| 21 | DR. MIDDENDORF: Guille Mejia?                                    |
| 22 | MS. MEJIA: I'm here and no changes.                              |
| 23 | DR. MIDDENDORF: Carol North?                                     |
| 24 | DR. NORTH: (No response)   |
| 25 | DR. MIDDENDORF: I don't believe she's going to be on. Okay.      |
| 26 | Julia Quint?   |
| 27 | DR. QUINT: Here, and no changes.                                 |
| 28 | DR. MIDDENDORF: Bill Rom?  |
| 29 | DR. ROM: Here, and no changes.                                   |
| 30 | DR. MIDDENDORF: Susan Sidel?                                     |
| 31 | MS. SIDEL: Here and no changes.                                  |
| 32 | DR. MIDDENDORF: Glenn Talaska?                                   |
| 33 | DR. TALASKA: Here and no changes.                                |
| 34 | DR. MIDDENDORF: Leo Trasande?                                    |
| 35 | DR. TRASANDE: (No response)                                      |
|    |  |

1 **DR. MIDDENDORF:** He said he would probably be on around 2:00, 2 so he's not here vet. 3 And Liz Ward? 4 **DR. WARD:** Here and no changes. 5 **DR. MIDDENDORF:** Okay. Virginia Weaver? **DR. WEAVER:** (No response) 6 7 **DR. MIDDENDORF:** Okay. Virginia? 8 **DR. WEAVER:** (No response) 9 **DR. MIDDENDORF:** We have 12 present. That gives us a quorum. 10 Okay. 11 I also want to remind --12 **THE OPERATOR:** Hello, I'm going to put Steve Cassidy on, please. 13 **DR. MIDDENDORF:** Okav. 14 **THE OPERATOR:** Thank you. 15 **DR. MIDDENDORF:** Steve, we just did the roll call. Are you there? 16 MR. CASSIDY: (No response) 17 DR. MIDDENDORF: Steve? 18 MR. CASSIDY: (No response) 19 **DR. MIDDENDORF:** Is Steve Cassidy there yet? 20 MR. CASSIDY: (No response) 21 **DR. MIDDENDORF:** Okay. Hopefully he'll let us know when he 22 comes on. 23 Okay, we do have 12 now. The amount we have is a quorum. 24 For voting -- I just want to go over the motions and voting 25 procedures. When a member of the Committee is developing a 26 motion what I'll do is I'll type it here on the computer so that it's 27 visible on the screens for those who are logged in to the web 28 conference, and each of you should be able to see it that way. 29 When the Chair calls for a vote I will have to do a roll call vote and 30 I'll ask each of you in turn to say yes, meaning you are voting for 31 the motion that had been put to the Committee; or no, meaning 32 you are voting against the motion that had been put to the 33 Committee; or abstain, meaning you are not voting on that 34 particular motion. If they recuse for a specific motion, I'll note that 35 also.

1 I just want to remind everyone that, according to our bylaws, the 2 majority of those voting determines the outcome. 3 So with that, I'll turn it over to Liz. 4 **DR. WARD:** Hi, and I'd like to add my welcome to Paul's. I think we 5 should probably proceed directly to John Howard's comments because of the 1:10 deadline for beginning the public comment. 6 7 **DR. HOWARD:** Great, thanks, Liz. I appreciate that. And good 8 afternoon and good morning to every Advisory Committee member 9 and to all the members of the public, responders and survivors, 10 other attendees at the meeting. I just want to first of all thank 11 each Committee member again for your service. Your time and 12 your advice are greatly appreciated. 13 As I mentioned at your inaugural meeting in November 2011, the 14 Committee has an important role to play in the World Trade Center 15 Program. The James Zadroga Act specifies three general areas of contributions from the Committee, and only three. 16 17 The first is providing input on eligibility criteria for Pentagon and 18 Shanksville responders, and modified eligibility criteria for 19 responders or survivors. The Act requires that, before making a 20 determination establishing eligibility for Pentagon and Shanksville 21 responders, the Administrator must consult with the Committee. 22 As you'll recall, we did this at the last meeting, February 15th, and I 23 want to thank the Committee for its consultation on the eligibility 24 criteria for Pentagon and Shanksville responders. At the present 25 time the regulatory language to add that eligibility criteria is being 26 prepared and will appear in a future Federal Register notice, as 27 well as on the World Trade Center website. 28 If the Administrator decides to consider modifying current 29 statutory eligibility criteria for New York City responders, then -- as 30 the Act requires -- the Administrator is required to consult with the 31 Committee for input. 32 In the case of changes in the survivor eligibility the Act requires the 33 Administrator consult not only with the Scientific Technical 34 Advisory Committee but also with the steering committees and the 35 data centers. At this time the Administrator is not planning to do

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any modification to the current statutory eligibility criteria. The second major area is identifying research needs. As I mentioned before, Section 3341(c), pertaining to research, requires the Administrator seek advice from the Committee. I want to thank the Committee for its consultation provided at the February meeting. On March 23rd, 2012, a funding announcement was published for cooperative research agreements related to the program. The receipt date for applications is May 21st, and a link to the announcement can be found at grants dot NIH dot gov. And thirdly, the third function of the Committee is providing a recommendation regarding addition of conditions to the list that is in the statute. As you are aware, we received a petition to add cancer to the list of statutory conditions on September the 8th, 2011 and, pursuant to the Act, the Administrator requested the advice of the Advisory Committee and provided a due date for the recommendation of April 2nd, 2012, which is 180 days from the date that the Administrator's request, which is in fact the maximum amount of time permitted by the Act for the Committee to submit its recommendation.

The Act provides that not later than 60 days after receipt of the Committee's recommendation -- which, according to the calendar, counting calendar days, would be June 1st, 2012 -- the Administrator must publish in the <u>Federal Register</u> a proposed rule with respect to the Committee's recommendation, or a determination not to propose a rule and the basis for such determination. As I said at your November meeting, it's important to keep in mind as you deliberate today that the Committee was established by the Act to provide advice of a scientific or technical nature. Articulating the strongest possible scientific basis for the Committee's recommendation on Petition 001, including an evaluation of available information about the level of exposure to carcinogenic agents, will be of the greatest value to the program. And certainly I look forward to receiving your recommendation on Petition 001 by April 2nd, 2012, and will give it the fullest and most serious consideration.

Finally, some Committees -- Committee members have asked what does the Committee do after April 2nd, 2012. And as I just stated, the Act provides only consultative actions for the Committee in relation to the Administrator's determining or modifying eligibility criteria, preparing input for research solicitations, or determining whether to add health conditions. So the Committee has a limited role and meets only at the request of the Administrator based on these three program needs. If there's no business to conduct with regard to the Committee's consultative duties, then the Administrator will not request the Designated Federal Official to call a meeting.

So again, on behalf of the entire program, thank you very much for your service on the Committee and I wish you a very successful meeting today. Thank you, Liz.

**DR. WARD:** Thank you, John.

#### **PUBLIC COMMENTS**

Paul, I'll turn it over to you for public comments.

**DR. MIDDENDORF:** Okay, let me check real quick -- Steve Cassidy, are you on the line?

MR. CASSIDY: (No response)

**DR. MIDDENDORF:** Steve, are you there? You need to -- Steve, if you called in to the general line, you need to call back, you know, on the --

MR. CASSIDY: I am -- I am here.

**DR. MIDDENDORF:** Oh, okay, I just couldn't hear you. Okay, great. Just wanted to check and make sure you were here.

MR. CASSIDY: I'm here, thank you.

**DR. MIDDENDORF:** All right. Okay, moving on to public comments. Each of the public commenters have signed up on a first come, first served basis and each of them will have up to five minutes to present. I'd like to remind folks that five minutes can go by fairly quickly, so in four minutes I will let the commenter know that they have one minute remaining so they can be sure to make the point they need to. If they haven't finished in five minutes, I have to rudely interrupt them and thank them for their comments. I

apologize up front to everyone to whom that happens, but we have to do that to be fair to all our presenters and to stay on time. So I want to point out that you do have the option of submitting written comments to the docket for this Committee. The docket number is 248, and the information on how to submit that is both on the NIOSH docket web page and on the Committee website. The last thing I need to do before beginning the comments is to make sure the commenters are aware of the redaction policy for public comments. The policy is in the Federal Register notice for this meeting, and it's also on the Committee's web page. The policy outlines what information will be kept and what information will be redacted before it's posted to the docket. So with that, let's go to our public commenters, and our first commenter is Jim Melius.

DR. MELIUS: Okay. Thank you, Paul, thank the Committee. I'm Jim Melius. I'm from the New York State Laborers Union. I'm also chair of the steering committee for the responders' medical program. First of all I'd like to thank the Committee for all of your efforts in working on this issue, responding to the petition, drafting your recommendations and -- I think very importantly -- drafting the -really developing and drafting the scientific rationale for these recommendations. I realize the amount of effort involved. You didn't have a pattern or template to follow, and I really think that you've done an excellent job of developing this draft document in a very short time. So I appreciate it and I know others do also. I have a few brief comments I'd like to make. One issue that came up, at least in the development of the document, was some concerns were raised about the cost and administrative burdens of adding some number of cancer sites to the list of covered conditions, and I really think -- feel very strongly that that's -really shouldn't be a consideration for this Committee. You're only asked to review the scientific evidence involved, and I think that the implementation of your recommendation and issues related to that are something that really is up to NIOSH and to the World Trade Center Administrator to address going forward. So I really

don't think that should be a consideration, nor should the cost of treatment or -- or issues like that are not something that should be part of your review process.

That I -- again reminding that there's also a second step to this process, that once a condition is added there's still a diagnosis and attribution of a particular -- in a particular patient of whether or not that cancer is World Trade Center-related and a certification of that attribution by the World Trade Center Administrator. So I think the administrative issues can be dealt with through that. And again, it's not everybody with the conditions that are included in the program. There -- there is a second step to this.

Secondly, I'd like to raise an issue of -- you already have it partially covered, but I recognize that you're not in a position to review data that's not been published yet, but you do acknowledge that there are studies that I believe both have been submitted for publication and for public -- that's both the Registry and the Mount Sinai Program, and -- and I -- you have a general recommendation that the Administrator should take those into account. If there's a particular cancer site that you're discussing and whatever, you think there's a particular issue that they should address based on those, I think this may come up for prostate and thyroid cancer, I would make -- do that as a specific recommendation 'cause it's well possible that both of those studies will be published by the time that the Administrator is in the process of developing his recommendation and his Federal Register notice. And so those may be very well available by that time and could well be considered in that process.

Finally, I would just point out particularly two cancers that are left off your list as we -- as I understand your report. One is breast cancer, which -- I realize there's not a great deal of literature linking breast cancer to occupational exposures, but I think we all have to recognize that that is a result of the fact that there were very few women working in most of the industries, at least in the past, where cancer was studied and where there were exposures to many of these carcinogenic agents, and --

**DR. MIDDENDORF:** One minute, please.

**DR. MELIUS:** -- I'm not sure that there's been a, you know, sort of a fair assessment of that. And I would ask you to sort of reconsider that. I believe you have a -- sort of set aside the -- an issue of female cancers, and I think that is -- probably falls under -- under that particular subject.

The second cancer I'd ask you to reconsider is brain cancer. Again, the literature may not be as strong as it is for some of the other cancer sites, but certainly it's something that's repeatedly showing up in studies of firefighters, as well as in petrochemical workers in the past and ongoing studies and it is something that -- I think there's a fair amount of evidence that it's related to chemical exposures, though again maybe not as strong as some of the other cancers you've listed and I think that deserves some reconsideration. So --

**DR. MIDDENDORF:** That's five minutes.

**DR. MELIUS:** -- thank you for your efforts and good luck going forward this afternoon.

**DR. MIDDENDORF:** Thank you, Jim. Our next public commenter is Lila Nordstrom.

MS. NORDSTROM: Hi, I'm here. Should I begin? I was a student at Stuyvesant High School on 9/11 and I'm the head of Stuy Health, which is an advocacy group for Stuy alumni who were there on that day. We were just three blocks from the World Trade Center and we were inside of our building until about 10:30 on the day. A lot of us left the building after the dust cloud had already reached Stuyvesant, and then later the school was used as a command center for the rescue effort and not adequately cleaned ever before we reoccupied it on October 9th in 2001. It was only three weeks after the attacks. There was smoke and ash blown into our school daily, and the barge -- the garbage barge for the debris was right next to our school. It was right next to our air intake system, and environmental testing showed that levels of particulate matter outside Stuyvesant were often higher than they were at Ground Zero.

I wanted to talk a little bit about some of the health conditions that members of Stuyvesant are experiencing -- sorry, I'm on the street and there's cars coming all of a sudden. Acid reflux and coughs and respiratory problems were already pretty widespread among the Stuyvesant population, but we have anecdotal reports of cancers that are growing, as well as some autoimmune disorders. In the last five years at least six cancers have been reported to me by former classmates.

Nick Friedlander\* from the class of 2002, I'm sure you've heard from before, was diagnosed with Hodgkin's lymphoma in 2006. He'd had severe flu and cold-like symptoms for years, and he believes that environmental factors played a part in his diagnosis. Howie Salz\* from the class of 2002 was diagnosed with non-Hodgkin's lymphoma last summer, in August. She went through six rounds of chemotherapy over the course of four months. She's a teacher. She was unable to attend work at all during that time and she's in remission right now, but her treatment caused her to develop blood clots in her heart and a clogged vein near her heart, so she's on blood thinners and she's getting monitored every few days by giving blood.

Courtney Hughes from the class of 2002 has had two major surgeries in the last six years to remove multiple synthroidonomas (sic), which are benign tumors. She had them on both of her ovaries. These types of benign tumors are really rare in younger women. She had no family history of this. And in some cases these cysts actually turn out to be cancerous. She's been told that they'll likely keep growing back and require further surgeries, and the last surgery that she had she almost had to have while she was pregnant. She ended up going under the knife three months after giving birth, and she also believes that environmental factors played some role.

There's also a thyroid cancer in the graduates of class of 2002, and then for the class of 2003 the <u>Columbia Spectator</u> in 2007 reported that Sam Cross was diagnosed with acute myelogenic leukemia, which is a really rapidly-growing cancer in the blood and bone

marrow. It's normally found in much older adults than he was at the time. He was in college at the time, and he had to have a bone marrow transplant.

And then we also have reports of a melanoma from the class of 2003. It was removed, it hadn't spread and it was removed in 2009.

But these are just the cases that we know about anecdotally. There are surely more than this, especially in the younger classes who -- who, you know, are younger than the class of 2002 and 2003, and will probably develop similar conditions in the future. There's already four cancers from my class alone, and that's in addition to the numerous other 9/11-related health conditions that people are reporting from these classes.

None of these cases have visited the 9/11 Health Center because they spend their whole lives at the doctor's and they, you know, don't necessarily have the ability to spend a full day getting treatment for something that is not their main health problem. But

**DR. MIDDENDORF:** Four minutes.

MS. NORDSTROM: -- it's really important -- it's really important that they be able to be treated at these centers. You know, we're -- we're at an age where we're -- you know, high numbers of us are uninsured. We're spread out all over the nation. A lot of us are already being excluded from health coverage based on 9/11-related preexisting conditions. I personally have had that experience in California and I know other classmates of mine have as well. So it's -- these cases are certainly going to keep appearing and there are certainly already an alarming number, so it's really important that we have somewhere to go where we can get treated for these conditions, and also so that we know what to expect, you know, so that we know what the rest of the students at Stuyvesant should be looking out for and how -- how these conditions are, you know, going to affect us in the future.

I think that's it for me. Thanks so much --

**DR. MIDDENDORF:** Thank you very much.

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MS. NORDSTROM: -- for your time. Okay, bye.

**DR. MIDDENDORF:** Our next presenter is Micki Siegel de Hernandez.

MS. SIEGEL DE HERNANDEZ: Hi, thank you, Paul. My name is Micki Siegel de Hernandez. I'm the Health and Safety Director for the Communications Workers of America in District One. Our union represents different groups of 9/11 responders, as well as area workers affected by the events of 9/11 and subsequent exposures. The Committee should be commended for the work that went into the draft recommendations. There was clearly an enormous amount of thought and effort put into the draft. And the body of scientific evidence that was compiled in such a short amount of time is impressive. The STAC should also be commended for recognizing in this draft that the lack of quantitative exposure data is not evidence of a lack of exposure.

Our union advocates the inclusion of all cancers in the list of World Trade Center covered conditions, and believes there is ample rationale for that recommendation.

On page two of the draft -- the STAC draft -- it says, quote, 'Many substances present in World Trade Center dust and smoke have been classified by IARC as known, probable, or possible carcinogens based on animal studies and mechanistic data, and the Committee believes that such evidence is highly predictive for human carcinogenicity. However, because there is limited concordance between specific cancer sites affected in humans and animals, only those substances classified based on human data are informative regarding organ sites of carcinogenicity in humans' end quote. Therefore, many World Trade Center contaminants for which the evidence as recognized by the STAC as highly predictive for human carcinogenicity were removed from consideration in the STAC's deliberations because specific cancer sites in humans could not be determined.

Instead, I would urge the STAC to reconsider this and recognize that the presence of multiple carcinogenic substances supported by IARC documentation, scientific documentation, and known to have

been present in World Trade Center contamination but for which human cancer sites cannot be predicted, as lending scientific credence to the inclusion of all cancers. If instead the Committee decides to include only certain cancers and exclude others, it is then incumbent upon the Committee to provide stronger support than is in the current draft as to why those cancers not recommended for inclusion could not be considered potentially World Trade Center related.

And lastly, I want to echo what Dr. Melius said earlier and to remind the STAC that the list of World Trade Center covered conditions is not presumptive for any of the diseases currently on the list, and similarly will not be presumptive for cancer. It will still be up to a treating physician to determine World Trade Center relatedness and attribution for any given individual based upon many, many factors, including an individual's personal and medical history, World Trade Center exposures, temporality of disease onset or exacerbation, medical exams, test results, co-morbidities, et cetera.

Thank you.

**DR. MIDDENDORF:** Thanks, Micki. Next commenter is Frank Tramontano.

MR. TRAMONTANO: Hi, good afternoon, this is Frank Tramontano from -- from the Patrolmen's Benevolent Association. This Committee has heard testimony about how the sampling data for the various carcinogens at the World Trade Center site were limited and how no samples were collected until four days after 9/11. Testimony also revealed how the samples were collected not to capture the highest exposures and not in a manner to estimate exposures for workers on the Pile. The Committee still only has one cancer study published to date to use in making this decision on the inclusion of cancers. Despite these shortcomings, this Committee in its March 18th draft has determined there is sufficient evidence to confirm that those who were exposed to carcinogens at the World Trade Center site have an elevated risk of developing cancer. However, the draft document arguments (sic)

against recommending all cancers be covered. Some of those arguments presented against recommending all cancers are based on resources required to implement such a recommendation, while other arguments project how cancer patients and health providers would react. We feel these arguments should be considered outside the scope of the Committee's charge.

We support and strongly agree with the arguments presented in favor of adding all cancers. Some of these arguments include the large volume of toxic materials present in the World Trade Center, the presence of multiple exposures and mixtures with the potential to act together to produce unexpected health effects, the major gap in the data with respect to the range and level of carcinogens and the limitations of testing for the carcinogenic nature of the many chemicals and agents identified at the World Trade Center. These arguments, along with some of the key findings in the FDNY study, are more than sufficient to support all cancer recommendation to the program Administrator.

After ten and a half years, the only cancer study completed is the FDNY study. This study does not include data beyond 2008, and the surveillance bias included in that study reduces the data back to 2006. The fact that the cancer cases identified in the surveillance bias were not early stage tumors and that Dr. Prezant has testified before this Committee that the non-exposed group have a good rate of participation in the FDNY monthly program should suggest -- should question the relevance of the surveillance bias.

Additionally, both the Mount Sinai and the New York City
Department of Health cancer studies, which have been promised to
this Committee but have yet to come out, appear to support the
findings of the FDNY study, despite those studies having some
serious limitations, not the least of which is failing to include 70
police officer responders that we know were diagnosed with cancer
within the time frame covered in these studies.

Yet despite having only one study with the new qualifications, we believe there is sufficient scientific and medical evidence that

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exists to support adding all cancers. We base this belief on the fact that the FDNY study showed that the increased growth in cancers of exposed firefighters versus non-exposed firefighters was significantly higher in the later period of the study, from 2005 to 2008, than it was in the earlier period. Furthermore, it is logical and acceptable for this Committee to accept that difference to grow, thus establishing an even greater support for all the cancer recommendation -- for an all-cancer recommendation. It would be helpful if this Committee had an updated analysis through 2011 from the FDNY, using the same standard as in the original cancer study of self-reported cases that have pathological confirmation. The Committee's recommendation -- recommended approach is to vote on individual cancers. This approach appears to leave out at least two cancers that we believe there is evidence of being WTCrelated. The PBA has eight brain cancers -- cancer cases reported to us with an average age of diagnosis of 36. The annual national average is 6.5 per 100,000 with an average age of 56. Clearly the average age for diagnosis that we have suggests something unusual. We are asking that an immediate review be done on all the brain cancer cases compiled by all the brain -- by all the cancer study groups to determine the real rate of brain cancer among the responder population.

Pancreatic cancer is another cancer we believe warrants a more comprehensive review before it's left off the list. The PBA has six pancreatic cancer cases reported to us with an average age of 48, and the FDNY cancer study lists five pancreatic cancers. The same issues can be raised with the cancer -- with this cancer, with our average age of diagnosis being 48, when it is 72 among the general population --

**DR. MIDDENDORF:** One minute.

**MR. TRAMONTANO:** -- suggesting that this, too, is a cancer that demands immediate review.

Additionally, we do not -- we do not understand why pancreatic cancer isn't being recommended for approval since it appears to meet the Committee's specific criteria of arising in regions other

1 than the digestive tract. This Committee has a responsibility to at 2 least recommend that a further review be done on these two 3 cancers and the results be reported to the program Administrator. 4 We must remember there are real lives that hang in the balance, 5 making it worthy of a more comprehensive review. Finally, we must remember that while the information before this 6 7 Committee hasn't changed in the last six weeks, there have been 8 changes in the lives of responders who have -- who are being diagnosed with cancer. It is exactly for this reason Congress has 9 10 mandated that cancer -- that this cancer issue be reviewed. The 11 men and women who responded that day who are sick with cancer 12 today and need treatment are relying on this Committee to leave 13 no stone unturned in their review of the medical and scientific 14 evidence establishing the exposure between responders and 15 cancer. It is for these reasons we request the Committee to 16 require an additional review for brain and pancreatic cancer if they 17 choose today not to approve those cancers for treatment. 18 Thank you. 19 **DR. MIDDENDORF:** Thank you very much. Our next presenter is 20 Mary Perillo. 21 MS. PERILLO: Hello? Can you hear me? 22 **DR. MIDDENDORF:** Yes. 23 MS. PERILLO: Okay. Do you have my pictures? 24 **DR. MIDDENDORF:** Yes. When you tell me to put them up I will try 25 to bring them up on the web conference. 26 MS. PERILLO: Okay, let's start with number one. 27 **DR. MIDDENDORF:** It doesn't look like it's going to work. There 28 appears to be something wrong with the photograph. Let me try 29 the second one -- no, there seems to be a problem with them. 30 MS. PERILLO: Okay. Is there a way that they can be entered into 31 testimony with my --32 **DR. MIDDENDORF:** We can attach them at the end of the docket, 33 yes. 34 MS. PERILLO: Yeah, okay, great. Then I'll just --35 **DR. MIDDENDORF:** I'll ask you to send me a new copy of them.

MS. PERILLO: Okay, that's fine. On September 11th my building, which is on the south border of the World Trade Center site, was very much involved. A number -- it remained standing, but a number of the windows -- all the windows on the west side and the north side and a couple of other windows in the building were blown in. And along with the windows blowing in, a tidal wave of World Trade Center debris also blew in the broken windows that included things from the sizes of 11-foot window flashings and computers, corners of desks, rugs, phones, to things in particle size so small as under -- what was it, what was our old number size? It's been such a long time since I've done the numbers. We needed to be clean below -- Kimberly, help me -- so many microns. But whatever it was, we were way -- we were way off the charts in terms of what was safe to breathe, even though at the time we were being told that it was okay to go back in. And we went back in with police escort to try to dig through the say three-foot deep in the corner piles of dust and debris and find, I don't know, personal photographs, my mom's engagement ring -- we went through to find things at first.

And then we went through and worked for weeks and weeks and weeks shoveling because our landlord said that he wouldn't clean the building unless it was empty -- and empty of everything but solid wood or metal. So we started doing that, all the while pleading to the EPA and the DEP and the DEC and anybody who would listen. I called the USGS and UC California Davis to see if we could get numbers, tests and help with the cleanup. When we finally found out that we had pretty much everything that Deutsche Bank had in our apartment -- the pile was basically in our apartments -- I called an old geology professor and he sent someone to estimate a proper cleaning of my space, which was \$26,000 so that was pretty impossible.

And then finally the EPA was convinced by the community to assist with the cleanup, and we were one of the test buildings for the cleanup. September 15th, 2002 was the day our cleanup began, so in the year before that we spent a lot of time not living in the

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building but clearing out the building ourselves. And without electricity and water, we weren't doing a very good job of it and we were taking it all to wherever it was we were living at the time. So when our cleaning began it was a year and three days later, something like that, and it was three shifts a day, seven days a week for a month to clean one 12-story building with about 20 apartments. And mine failed three times in a row. It didn't clear three times in a row and had to re-clean it, re-clean it, just basically hosed it down till there was nothing left but water on the walls, and I even tore some walls down to make sure that walls that were perfectly flush to the floor were not harboring stuff I'd have to breathe for the rest of my life in the building where I still live. The best -- the best I can remember about the chemicals in our dust is that it exceeded pretty much every exceedence (sic) that was found in all the other places that were tested. I still own some of the dust in a baggie. If anybody would like to test it now you can have new samples. I don't know what happens to it after more than ten years, but I know that there are two people in a lab who know the numbers on what we had, and I know that we were exposed to way too much, way too small particles for way too long, and I really hope that you do add the cancers to the list, and also that you add the community that was exposed. We really are very grateful to the first responders who were there, and we were there, too. We were next to them.

Okay? Thank you.

**DR. MIDDENDORF:** Thank you very much, Mary.

MS. PERILLO: Okay.

**DR. MIDDENDORF:** Our next presenter is Jo Polett.

MS. POLETT: My name is Jo Polett and I live seven blocks north of the World Trade Center site. I'm impressed by the Committee's grasp of the complexity and variety of toxic exposures within and across the populations with which the master draft is concerned. I do, though, have a couple of edits that I hope you'll accept. On page 11, lines 18 and 19, the document states 'Dust entered buildings through broken windows, open windows and air intakes.'

The fact is dust also entered buildings through closed windows. Given the mass and force of the collapse cloud, buildings in its path acted as sieves for the dust. So while a lot less dust entered a building through a closed window than through a broken or open window, the dust that made it through closed windows had proportionately higher amounts of very small, highly respirable particles. I ask that you amend the statement to read 'Dust entered buildings through broken windows, open windows, closed windows and air intakes.' An additional advantage of the proposed correction is that it broadens the statement to cover the smokeborne particles referenced earlier in the draft that permeated the closed windows of lower Manhattan buildings for months following the attacks.

For the second edit please go to page 18, line 16 of the draft. Quote, 'The US EPA did not find elevated levels of TCDD and house dust,' end of quote. I understand that the aim of the paragraph is to lay out the various conflicting findings regarding the quantities of dioxins, furans and PCBs released by the attack in its aftermath. Indeed, the sentence in question is immediately countered by a sentence referencing the window film analyses that found high levels of TCDD adhering to the outside of windows in buildings within one kilometer of the site. However, the implication is that the US EPA findings and the window film analyses deserve equal weight. They do not. EPA scientists were constrained by EPA's liability concerns. The Canadian team that conducted the window sampling had no such constraints. Further, the EPA finding is not sourced, though I expect it will be in the discussion that follows. In any case, before an EPA finding can be accepted as credible, the sampling method must be reviewed and the conduct of the method must be assessed. In cases where it's not possible to charter a time machine and watch EPA collecting the samples, negative findings must be considered suspect.

I know this because I was present when EPA sampled my apartment for heavy metals and dioxins during the first test and clean program that launched in May of 2002. When I saw that the EPA

sampling technicians were setting up to collect the samples from my kitchen counter, I insisted that they collect the samples from a surface more likely to harbor contaminants. After a lengthy argument, the technicians agreed to collect the samples from the wood floor of my bedroom instead of the kitchen counter. As reported at the first meeting of this Committee, the wide sample results from my bedroom floor was 127 micrograms per square foot. The results for antimony was 1090 micrograms per square foot. Had I not been present during the sampling and fought with EPA's technicians, the presence of WTC-derived heavy metals in my apartment would have gone undetected. For support of my contention that EPA's WTC findings were constrained and corrupted by EPA's liability and policy concerns, I refer you to the summary report of the US EPA technical peer review meeting on the draft document entitled 'Exposure and Human Health Evaluation of the Airborne Pollution from the World Trade Center Disaster.' The peer review committee met in July of 2003 and published its report the following December.

**DR. MIDDENDORF:** One minute, please.

MS. POLETT: A major purpose of the EPA's document was to obfuscate the difference between conditions indoors and conditions outdoors and state, quote, 'Except for exposures on September 11th and possibly during the next few days, persons in the surrounding community were unlikely to suffer short term or long term adverse health effects.' Peer reviewers unanimously rejected this ploy, insisting that EPA make a clear distinction between exposures to ambient air and indoor and occupations exposures. They took the additional step of suggesting that EPA convene an independent group such as the National Academy of Sciences to analyze the indoor air data because they were so discouraged by EPA's use of suspect data to support its analysis of indoor air conditions.

**DR. MIDDENDORF:** Five minutes, Ms. Polett.

**MS. POLETT:** I ask that the Committee appropriately qualify the EPA finding in question or delete it from the paragraph entirely.

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Thank you.

**DR. MIDDENDORF:** Thank you very much. Our next presenter is T.J. Gilmartin.

MR. GILMARTIN: Yes, T.J. Gilmartin here. I'm 31 years as a shop steward with United Cement Masons Union in New York building high-rises. I've already spoken once before at the federal plaza. Now I just want to reiterate that in the 31 years that I was on a construction site, everything that was at the Trade Center according to the OSHA standards, I just can't see how they can't put some of these OSHA standards to everything that was down there -- the silicas, the dust -- the concrete dust, the asbestos. I mean this is all stuff that, when I was on a construction site, I would have got locked up or fined very high if I didn't have respirators on and all. I mean just common sense tells me if you're putting up these buildings and they have such high standards for us putting up the buildings, what happens when two of them come crashing down all at one time? And these buildings -- I mean it's just common sense.

And you know, I just want to thank you for all the intent, everything you've done, and I just want to add one other quick point, that as much as you're doing this, I really appreciate it.

Don't let -- there's a lot of people coming out of the woodwork.

Even if you add this cancer and these cancers get added, you're going to have everybody and their mother, pardon my French, coming out of the woodwork, swearing that it was from the World Trade Center. There are some real heroes that deserve -- deserve to be taken care of, but there's als-- don't let the frauds discourage you from what you're doing. You guys do a great job.

And now when -- I've got a few minutes. I have somebody else to speak in my -- the rest of my time spot.

**UNIDENTIFIED:** Here is Chris Kraft, giving up T.J.'s time.

**MS. KRAFT:** My name is Christine Kraft. I am a retired clinical social worker. On 9/11 I was already retired from my job and I was a member of the Red Cross Disaster Mental Health Team. And as such, on 9/11 we were dispatched down to Ground Zero, I had full

Ground Zero clearance. My job was to go down to Ground Zero to take care of all of the first responders who were there, to make sure everybody was okay. I will tell you right now that I have several medical conditions. I have nodules in my lungs. I have Hashimoto's thyroiditis. I have GERD's. I have a blown sinus, and I have strange neuromuscular disorders. I was breathing that stuff for quite some time.

My sister-in-law, who was down there for four days, has thyroid cancer and she recently had half of her thyroid removed. I also personally know many other people who have Hashimoto's thyroiditis, as well as nodules of the thyroid -- which I also have -- which have so far not been diagnosed as cancer but there is a chance that it will. They told my sister-in-law there was nothing -- even after a biopsy was done, they said it was probably not -- not cancer, but it turned out that -- she chose to have the surgery and it turned out to be cancer as well.

I know a friend of mine who was 12 years old and a student in the area at the time, she now has thyroiditis as well, Hashimoto's. This is a common disorder of middle-aged women. She is 20 years old. I also know someone else who lived in the building that was near the World Trade Center. She is a guide down there as well, and she now has Hashimoto's as well. She is under the age of 40. Nobody in my family or any of my friends' families ever had any problems with the thyroid. Before that I was a runner. I was very healthy, and I never thought in a million years that this would happen to me. But at the same time, what we were breathing there, and I'd like to follow the gentleman that was recently up, I can stand in a room with second-hand smoke and that exposes me to lung cancer. But I was in the pit of hell with every -- every substance known to man and breathing that outright for days and days on end and that doesn't cause cancer at all.

**DR. MIDDENDORF:** One minute, please.

**MS. KRAFT:** It's the logic that -- that it would be. Thank you very much for your time.

**UNIDENTIFIED:** Thank you. Joe Morrone, a downtown resident, is

1 going to use the remaining minute. 2 **MR. MORRONE:** Hi, my name is Joe Morrone. I'm a resident of 3 Southbridge Towers. At the time of the attacks on the Trade 4 Center I worked on the New York Stock Exchange floor, and I was 5 President of the Board of Directors of Southbridge Towers. So -and that was right in the line of all that smoke and everything. I 6 7 was just recently -- I remember the CDC coming down with Nadler 8 to talk to the Board of Directors at the time, to talk to our co-op in 9 February of 2002, telling us that the air was clear. And just so you 10 know, I asked him to leave and not insult my intelligence because 11 we didn't know about what bomb we were breathing because it 12 was just asbestos or just PCB or just lead, I could understand it, but 13 with all the particles that we were breathing with the Trade Center being vaporized the way it was, I knew that eventually something 14 15 would happen. And ten years -- almost ten years to the day I was 16 diagnosed with a mass -- a real -- a mass on my kidney and --17 **DR. MIDDENDORF:** Your five minutes is up, please. 18 MR. MORRONE: I'm sorry? 19 **DR. MIDDENDORF:** The five minutes is up. Thank you very much. 20 MR. MORRONE: Thank you. **DR. MIDDENDORF:** Could I get the last gentleman's name, please? 21 22 **MR. MORRONE:** Sure, my name is Joe Morrone, M-o-r-r-o-n-e. 23 **UNIDENTIFIED:** And he lived and worked downtown. 24 MR. MORRONE: I worked on Wall Street, New York Stock 25 Exchange, and I lived there also with my children. 26 DR. MIDDENDORF: Okay, the name is Joe Morrone, M-o-r-o-n-e 27 (sic)? 28 MR. MORRONE: M-o-r-r -- double-r -- o-n-e. 29 DR. MIDDENDORF: Okay, thank you very much. Our next 30 presenter is Jacques Capsouto. 31 **UNIDENTIFIED:** Jacques Capsouto's right here as well. 32 **DR. MIDDENDORF:** Okay. 33 MR. CAPSOUTO: Hi, my name is Jacques Capsouto. I'm a resident 34 and business in Tribeca. I'm here to talk about Albert Capsouto, 35 my younger brother, who died of brain cancer -- I'm repeating,

brain cancer, which you have not included. He was diagnosed November 16th, 2009 and died January 19th, 2010, nine weeks after he got diagnosed. Albert was involved in the community, part of community board one, for 19 years. After 9/11 it became a fulltime job to reconstruct downtown, so if I get emotional... He was involved in four or five committees and he used to spend all his time going by bicycle downtown to the -- to the Ground Zero. He -sorry. He got diagnosed with gladioblastoma (sic) number four, which is a brain cancer, a mark of brain cancer. He died very quickly. The cancer really disabled him so fast that -- he deteriorate so fast that we didn't even have time to communicate. We -- we opened a restaurant in Tribeca and we stayed open and we fed people and we became a center for people to have -- for the community to be able to have a place to gather together, so we gave food away for 17 days. The name of the restaurant is Capsouto Freres and is at 451 Washington Street, and we reside at 457 Washington Street, which is in Tribeca.

And I hope that you take my statement as a testimony to include brain cancer. Please include it. He was very young and died very quickly, and I think...

**UNIDENTIFIED:** And he never moved out of the area, either. **MR. CAPSOUTO:** We -- we live in the area and then my mother -- we all of -- the whole family lives downtown and he's the only one that came out so quick, so fast. My mom also lived in the area, also died of liver cancer. They say there was -- they say there was health -- that it was no problem being downtown. We had the people from Con Edison bringing the dust to the restaurant. We had to feed the firemen coming in the first two, three days, coming in with the dust all over their clothes, coming into the restaurant. We had -- but Albert was really involved. He must have spent maybe three or four days going downtown on his bicycle to help the small businesses, to help reconstruct downtown. As a matter of fact, on October 28th of last year a park was dedicated to his name on the -- on Canal and Valley and Lake Streets. If you -- the park was the property of the Port Authority and he negotiated for

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the Port Authority to give the land to the Park Department and that's --

**DR. MIDDENDORF:** One minute, please.

MR. CAPSOUTO: -- the reason that the park was named after him. I think I've said enough, and I think -- I think you should consider brain cancer as another cancer to add to your list. I thank you. Have a nice afternoon and I hope you all do a good job on the -- on this Committee. Thank you.

**DR. MIDDENDORF:** Thank you very much, Jacques. I want to thank each of our public commenters for providing their perspective and their insight to the Committee, and it's always very helpful to hear from the people who live and work in that area. So on behalf of the Committee I want to thank each of you for coming and providing your information.

#### **DISCUSSION OF CANCER PETITION**

Before I turn this over to Liz, I just -- and as the Committee dives into the decision-making part of the meeting, I want to just take a minute to remind the Committee members what Dr. Howard mentioned in his statement about the need to articulate the scientific basis for their arguments. Looking out from the administrative perspective to add conditions to the list, he needs to know why a specific health condition or, in this case for this petition, cancer or a specific type of cancer should be added to the list of covered conditions. To accomplish this requires careful building of arguments based on scientific evidence to make the case for adding a specific health condition or cancer. That evidence -- it will come from the available information on exposure, epidemiology, toxicology, and it's important to understand that this approach is based on an examination of the best available evidence. It is not an approach based on merely presuming the cancer is a likely health effect that may result from the World Trade Center exposures. It won't be helpful to recommend to the Administrator that he presume that a condition should be added to the list unless the scientific evidence demonstrates that it shouldn't be on the list.

In moving forward, the Administrator will have to make the case for adding conditions, so the Committee will be most helpful if it presents the scientific arguments for adding conditions. If you want to say that another way, what the Administrator needs is for the Committee to answer the question 'Should this condition be added to the list?' for each of the conditions it decides to recommend for addition.

So I'll turn it back over to Liz.

**DR. TRASANDE:** Paul, may -- this is Leo Trasande. I apologize for interrupting but I realized I wasn't in at the earliest part of the call and I just wanted to document that I was here.

**DR. MIDDENDORF:** Okay. Thank you very much. So Liz? **DR. WARD:** Yes. So Paul and I talked a bit about how to best run this meeting, given the challenges of having this meeting be a teleconference, and also the need to really have a more formal style of meeting using Robert's Rules of Order, and my sugges-- or our suggestion is that we really look at the cover letter to Dr. Howard and go through -- go through it kind of in sequence and that -- so for example if it should talk about the first option of recommendations to include all cancers as World Trade Center-related conditions, the floor would be open for a motion to approve that recommendation, then a second, then there would be discussion, and then we would call for a vote.

With regard to the second option, there's a couple of ways that we can proceed on that. We can have a motion to accept the second op-- assuming that the first -- I mean if the first option -- the first option is approved by the Committee, then obviously we don't proceed to the second option, although we may talk about some ways that the information that was compiled for the -- in the second option might be used in the report. But -- but if the Committee does not vote to go with option one, then we'll move on to option two. And we can either consider option two as just accepting all of the cancers listed in option two, or we can have a motion to vote on each of the individual sites and site groupings that were broken out.

I assume it's also in order that we could entertain motions to add sites or organ systems that were not included in the draft cover letter. But one thing we have to keep in mind is that if we add a site or organ group, at this point we need to draft text that would support that recommendation because, as I understand this from Paul, essentially all of the writing on major points needs to be done at the meeting and not later.

I should also make you aware that I know that the draft that was

I should also make you aware that I know that the draft that was posted had some minor typographical errors and the references were not completely compiled. I've been working on that in the interim and, you know, we'll make every effort to make sure that the final document is properly formatted and doesn't include any errors.

So the way we're going to work this meeting is that Paul will actually be making the changes to the draft document that was circulated, or that was posted. And what I will try to do -- I want to be sure -- I know it's very difficult on these conference calls where, you know, a lot of people are trying to speak at the same time and if you're quiet like me sometimes you don't get heard. So what I'll try to do is, you know, if a number of people want to speak, I'll ask -- I'll take a minute and try to get a list of names so that I can be sure that everyone gets the opportunity to speak that wants to speak on an issue.

So at this point are there any questions before we open the floor for a motion to get started on discussing our recommendation -- any questions or overall comments?

**MS. HUGHES:** This is Catherine Hughes. I have a question of logistics. At what point in this conversation are we going to actually be voting for option one or option two?

**DR. WARD:** Well, when Paul and I talked about it, it was our thought that we would vote on option -- we would have discussion on option one and then vote on option one, because essentially if we vote in favor of option one, then option two is moot because we're not going to be voting on -- we're not going to be talking about a listing of specific sites.

MS. HUGHES: Okay, so if we're talking about option one, I wanted to draw everyone's attention to a *New Science* news article that came out at February 25th, 2012 which refers to the proceedings of the National Academy of Sciences that says bad stress is tied to inflammation, and that negative interactions may have biological effects. And it referred to two proteins that cause inflammation, that inflammatory triggers have been linked to increased risk of heart disease, high blood pressure, cancer -- which we're talking about today -- and depression. And the new results add to a growing body of research that links social stress to biological risk. So if -- 'cause I realized, when I was going through the testimony, we had not talked much about the mental impact on physical health. If one of our mental health experts could weigh in it would be much appreciated.

**DR. WARD:** Okay. But let's -- I mean it -- you know, maybe it's time to get a motion on the table regarding option one so then we can -- we can start the substantive discussion on that option? Anybody like to make a motion on option one?

**MS. SIDEL:** Well, actually I have a question. This is Susan Sidel. **DR. WARD:** Okay.

**MS. SIDEL:** You know, it's kind of hard to start talking about option one until I have an idea of what's going to be included on option two. Do you know what I mean? Like if -- if certain cancers that we -- that aren't there, if they're added, if there's a discussion about them and that if they're added it may change -- it could possibly change how people looked over at option one. I'm just throwing that out there.

**DR. WARD:** Yeah, I think -- I mean does anyone else have a similar concern?

#### (No response)

**DR. WARD:** I guess what -- you know, what we have to try to do, since we have kind of a limited time for the meeting and we really have only today to get this done, is to -- you know, to proceed as efficiently as possible. Now I guess -- and Paul, you could help me with this because I'm not really that used to running committees

with Robert's Rules of Order. I mean I guess if we are in the course of discussing option one, a number of people feel that they can't make a decision on option one before they have an opportunity to discuss option two and see what the final list of cancers would be, then we -- I guess we could -- you know, we can entertain a motion that we not vote on option one before we --

**DR. MIDDENDORF:** Yes, you can table the motion.

**DR. WARD:** We can table the motion.

**MS. HUGHES:** Catherine Hughes here again. Can we have clarification why brain cancer, pancreatic cancer and breast cancer's not, you know, being included?

**DR. WARD:** Well, I think at the end of the last meeting we -- the Committee recommended that we derive a list of cancers that should be included by reviewing three sources of information. One was the IARC list of cancer sites associated with cancer in humans for those sites -- for those exposures that were present at the World Trade Center, and that -- in our table, that is column one -- in our table four, that's column one.

And then the second -- second source was to review the areas of the body where there had been evidence of World Trade Center-related conditions that -- where chronic inflammation was part of the etiology or the cause for the -- for the biological process. And then the third was to look at the first epidemiologic study that was published, that's the firefighters, and look at sites that had any positive (indiscernible) at all in that study.

So we compiled the list from those three sources as accurately as -- I mean I did it and I assume other Committee members reviewed it. And then if it was -- if we got a positive signal from any of the three sources, then we included it in the list and we also discussed, you know, what -- we also in the cover letter we discussed what the level of -- what types of evidence were there and what the level of evidence was. So if it's not there, it means that -- so if brain and pancreas are not -- and breast are not there it's because we didn't pick them up from any of the three sources that we agreed on a priori.

1 Now that doesn't say that we can't now make a motion to include 2 one of those. What we were trying to do with this draft is simply 3 to follow the guidance that the Committee had with respect to how 4 to generate the list. 5 MS. MEJIA: This is Guille. DR. WARD: Hi, Guille. 6 7 MS. MEJIA: Sorry. Listen, I would like to make a motion that we 8 include all cancers, make a recommendation to the Administrator 9 that all cancers be included. And the rationale for including all 10 cancers that we use the option two rationale to justify our option 11 of including all cancers. So that's my motion. 12 **DR. MIDDENDORF:** I need specific wording to be able to put it up. 13 MS. MEJIA: Okay. That the STAC Committee -- the motion is is 14 that we recommend to the Administrator that all cancers are 15 covered, and that the rationale for covering all these cancers is the 16 basis for option two. You know, we used that information to justify 17 the coverage. 18 Sorry, I'm not very good at forming these motions. 19 **DR. WARD:** Yeah, we could say that we incorporate some of the --20 we incorporate some of the rationales from option two to develop 21 the rationale for option one. Would that capture what you're 22 recommending? 23 MS. MEJIA: Yes, Liz. Thank you very much. 24 MS. DABAS: Hi, Liz, it's Valerie. I second Guille's motion. 25 DR. WARD: Great. So now the floor is open for discussion and, like 26 I say, if it works out -- if it works out well that we're all speaking 27 and everything's working out smoothly, I'll just -- we'll go like that. 28 But if we need to start making a list, then we'll go that way. So the 29 floor is open for discussion. 30 MS. MEJIA: Well, if I could start -- this is Guille again --31 **DR. WARD:** Okay. 32 MS. MEJIA: -- I would just like to just state that, you know, we 33 have in these meetings acknowledged the magnitude of the 34 exposures that have been experienced by the responders and area 35 workers and the survivors to this toxic mixture. And you know, the

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lack of information -- as Micki has stated earlier, the lack of information in the literature is -- is really not enough to say that certain cancers should be excluded. And there are -- there are procedures in place to deal with whether this -- whether an individual's cancer will be covered by the treatment program. So you know, we shouldn't be worried about that, so -- I'll just leave it at that.

**DR. WARD:** Thank you. Anyone else?

MS. FLYNN: Yes, Liz, this is Kimberly and, first of all, you know, I want to thank you for taking the lead on this document. It's a remarkable document and it represents an extraordinary effort, primarily by yourself but also by the other experts. Nonetheless, I want to speak in favor of option one, in favor of Guille's motion to incorporate option two, and I think that the additional rationale that we can use for every cancer that is not currently listed in option two is quite simply the precautionary principle, which is sound science and recognizes that as our knowledge evolves it's going to lead us in a direction of understanding all the ways that aggregate exposures, cumulative exposures, synergistic exposures raise the risk of developing cancers. As scientific knowledge grows, so inevitably does the list of carcinogens. And almost without exception we will continue to see a steady lowering of the threshold at which exposures to carcinogens are known to have the potential to cause cancer. I just, you know -- I mean you've heard a number of people giving public comment today testifying in detailed ways about their exposure scenarios. You know, we heard about a restaurant where food was being served to returning members of the community and responders. You know, we will never know -- we will never have the kind of narrative that we would need to come to some kind of detailed judgment about all of the substances to which people were potentially exposed and all of the levels to which they're exposed. So you know, if as a child, unbeknownst to my parents who had to wait more than a year for an EPA cleanup, I was crawling on a carpet that was a reservoir for WTC lead, silica,

fibrous glass, there was also highly alkaline concrete dust, carpet fibers, along with some of the dust may have been coated with something like TCDD that's a carcinogen and a potentiator for other carcinogens. I may also have breathed PAHs in (indiscernible) fumes for weeks at my day care on Church Street. Exposures to PCP-172 which causes DNA hypermethyla-hypomethylation, even at low levels, might have come in my apartment windows in the first weeks following 9/11 and left an invisible film on the beanbag chair.

I just -- I think that, you know, the question of what would my post-9/11 cancer risk be is not something that we can nail down. And I do not think we should resolve uncertainties in favor of no effect. That's clearly what happened with respect to the government's judgments, and the result of that was that protections were not put in place and many, many people were unconscionably and unnecessarily exposed and are now sick. So I would say that, you know -- I mean actually I'm wondering if option one shouldn't be framed a little differently. I'm wondering if the truer path here wouldn't be to presume that all cancers are linked unless there is some definitive evidence demonstrating that a given cancer should not be linked.

**DR. ROM:** This is Bill Rom. Could I speak up?

**DR. WARD:** Yes, please. Thank you.

**DR. ROM:** So looking at all cancer, about five percent of all cancer is related to occupational exposures. That's probably occupational and environmental exposures, and I think we should try everything that we can to try to get to that five percent. But thinking of the other 95 percent, there's a lack of scientific evidence for those. We're supposed to be a scientific advisory committee, as well as technical, so I think we should really try to focus on those five percent and get some agreement on that. If we say all cancer is caused, then we should say acute myocardial infarctions, stroke, dementia, Alzheimer's and every other disease potentially should be causal. So I think we're overreaching, and I think we should really try to focus on those that IARC has demonstrated data and

3435

we have exposure data to match IARC, and try to make this scientifically rational so that we engender the respect that we need.

So I would vote -- I would recommend voting against the motion.

MS. SIDEL: I see that they don't -- is it okay to speak?

**DR. WARD:** Yes, thank you.

**MS. SIDEL:** You know, this is a really -- this is just such a tough issue --

**DR. HARRISON:** Susan, this is Bob Harrison. Would you talk up a little bit? I'm having trouble hearing you.

MS. SIDEL: Sure -- sure, sorry. Is this better?
DR. HARRISON: Yeah, that's a little better.

MS. SIDEL: Okay. I was just saying that this has just been tough because I feel -- I feel option one and option two, but the problem that I have with option two is that so much of the information is dependent on things like occupational studies or exposure data. And you know, occupational studies don't discuss women. Most of them are all about men so there's like a gender bias in there. And then a lot of the other problem I have is that the exposure data is so faulty that the chemicals that were there, that we could say this chemical causes X, we don't have that necessarily. We also don't know what the synergistic effect is of everything all together. So it's so hard to just choose option two and say -- because I just -- I feel as though there's so much potential for so many other kinds of cancers that we just don't have -- we just don't have access to the data that we need to support -- to support it. You know, for example, like breast cancer. You know, maybe the chemicals down there could cause breast cancer, but we didn't find that on the IARC chart. But does that not mean that combinations of the chemicals there could have caused it or just the whole -- you know. Then the other issue also is that what happens when your body is already so compromised, you know, by -- by the toxins? And even just following the other paths of inflammation and the diseases that have already been covered under the health -- the World Trade Center health bill, not everything is covered because not

everything has been explored. I mean there has never been the money or the time available to explore all the problems that people have. And you know, people get diagnosed, you know, outside of the program with things that should be included in the program, but it's just been impossible to do that. I mean the drug is new but we've been -- you know, we started under the Bush administration who were fighting tooth and nail for all health consequences, which is a lot of the reason why we don't have the exposure data that we need. So I don't know if that's scientific, but the science is that -- that it should be there, but it's not there and it's difficult to exclude something when you know that it's data that should be there although it isn't because it just happens to be the way things are at this point. Thank you.

DR. WARD: Thank you. Next speaker, please?

MS. FLYNN: This is Kimberly. I just want to speak up again in response to the idea that we should solely rely on the occupational literature. The occupational literature is extremely limited. Studies often look at -- chemical by chemical or in clusters of chemicals instead of taking account of the full breadth combinations and concentrations of chemicals to which residents, responders and survivors were exposed on and after 9/11. Occupational studies, as has already been pointed out, the occupational literature for the most part has not included women. It was developed at a time when women had not yet entered those types of jobs. Often occupational studies utilized OSHA standards, which occupational safety and health experts will tell you have a political component and are not as protective as they should be. And occupational exposures do not take into account sensitive populations or issues of genetic polymorphism. I guess I -- after I talked about the limits of occupational studies,

there actually is a 2010 study called 'Occupation and Cancer' in Britain that talks about shift work as an important risk in developing female breast cancer. So I don't know whether or not that made it into the IARC monograph, but we might consider it. At any rate, I think that using occupational literature, as I have said

in the past, as the sole basis or as even the main foundation of our decision means that we will be incorporating many of its flaws and limitations.

DR. HARRISON: Liz, this is Bob Harrison. May I speak?

**DR. WARD:** Yes, please.

**DR. HARRISON:** Okay. It's really a question, in consideration of the motion to approve all cancers, whether our advisory committee should take into consideration any statutory language or guidance from the Zadroga Act itself? In other words, what -- what criteria or scientific evaluation criteria should we be applying, if any, to consider these two options? Is there any standard by which we should consider this? Am I -- am I clear in my question?

**DR. WARD:** Yes, and I'll defer to Paul for the answer. I think we've talked about this before and the answer is really that the Committee is really being requested to develop the criteria as well as apply it. But Paul, would you like to respond?

**DR. MIDDENDORF:** Yeah, and if you're looking at the Zadroga Act for guidance in terms of how to make the decision, it gives very little. It basically says that the Administrator will need to review the scientific evidence to make his decision. So the Administrator has come to the science -- to the STAC and essentially has said 'I need you to help provide that scientific evidence so that I can move forward to essentially add covered conditions to the list.'

**DR. HARRISON:** Thank you, Paul. I would like to then speak in opposition to the motion to accept option one to cover all cancers, largely based on the concept that cancer is multifactorial. I think as suggested earlier by Dr. Rom, there are cancers for which there is substantial or other, more limited, scientific evidence for a relationship between occupational and environmental exposures than that cancer end point, and that departing from that principle by covering all cancers I think would be -- in my view, I think inconsistent or contrary to the -- you know, the best scientific principles, and I think would establish a -- represent -- that would -- that would really not -- not be consistent with other authoritative findings for a decision. I think, as Dr. Rom pointed out, would be a

-- sort of a leap, a departure. So I would -- I would argue against option one.

**MS. DABAS:** Hi, this is Valerie. I just had a question for the two people that are against option one. Could they name two cancers with absolute certainty that they would believe that have no environmental cause for those cancers?

**DR. HARRISON:** I would not. In fact, I think that's a -- this is -- that's a very good question. This is Bob Harrison again. I wouldn't be able to name cancers for which, with absolute certainty, there's no association or possible linkage between an occupational or environmental cause and that cancer. That being said, I think there are certain cancers for which, at this point in time, there's insufficient evidence to conclude that there is such a link. And I think that there's a difference between those two statements.

MS. DABAS: Well, my question in fact --

DR. HARRISON: For example, I would -- you know, if we get to the -- you know, if -- if we move on from option one, depending on the vote, to where we talk about specific cancers, I think we would have a discussion and debate about prostate cancer, for example, where I personally think that, although the evidence is suggestive, it doesn't yet reach the level of significance that I believe that we could link occupational/environmental exposures in many cases to prostate cancer. That's just an example -- which is not to say that there's not a linkage, but unless we were to have additional scientific evidence, perhaps from studies that are going to be forthcoming, I would suggest that there's probably -- the evidence for prostate cancer does not equal the evidence for lymphopoietic cancers or for aerodigestive cancers.

**DR. ROM:** This is Bill Rom. That's a complicated question that would take a whole course to answer, but there's limited evidence for prostate, for example. Breast has been a struggle for years to try to find some linkages and we're working really hard on that. Uterine cancer is another one that's a challenge. There's some rare uterine cancers like clear cell carcinoma are related to drugs and previous generations. Small intestine and skin -- we have one of

the more common cancers and, you know, beyond UV light and -Percivall Pott's scrotal observations we have very limited evidence,
so you have to go by site by site and histology by histology and
review all that. And we spend our lives trying to find the
associations and some of these are very difficult. Brain cancer, for
example, has been a challenge and we've been trying for years to
try to find environmental and occupational exposures for brain
cancer. And then there's a whole host of genetically-linked
cancers, and then some that are linked to viruses, and then diet is a
huge topic related to cancer. So it's a complicated question that
would take a long time to fully answer.

MS. DABAS: Thanks, Dr. Rom. I think Dr. Harrison answered it in that there's nothing we can say for sure with 100 percent certainty has no environmental links with cancer. So there's not one site that we can say with 100 percent certainty that there's no way that this person could have gotten it based on their environmental exposures.

**DR. TALASKA:** Hi, this is Glenn Talaska. I'd like to speak against the motion. I do believe that we need to provide the Administrator with scientific arguments in favor of adding diseases, as he requested. And I don't believe that the data are there that indicate that all cancers should be covered by -- with our recommendation.

**DR. DEMENT:** Hi, this is John Dement. Could I speak as well? **DR. WARD:** Yes.

**DR. DEMENT:** I'd like to also voice my opposition to the all cancers issue. I think we've been charged with providing a rational scientific basis for the selection of cancers to be included, if at all. And I think we've approached it from a perspective of the best evidence possible. I really think if we go the all cancer route -- although I'm very sensitive to the issue of rare cancers and there not being sufficient data because of their rarity -- I think we have the obligation to provide a sound scientific basis to the Administrator, one that can be incorporated without a lot of challenge.

I think we also need to be -- acknowledge when we do this that

there's a lot of uncertainty and there's a lot of area where, in the future, we should be continuously vigilant about sites that pop up, based on either studies of World Trade Center populations or studies elsewhere in the scientific literature.

MR. CASSIDY: Hello, this is Steve Cassidy. Hello?

DR. WARD: Yes, Steve, we hear you. Thanks.

MR. CASSIDY: I'd like to speak on the topic. Reluctantly I have to say that I don't agree with all cancers either. I'd like to be there. I recognize that those who suffered the most severe exposures are more likely to come down with cancers that are not yet defined in Dr. Prezant's study. I want to remind everybody, and I think they all know it, that the study goes back to really just 2008. And when you look at that study you have to recognize that there were a lot of people probably had cancer in 2007, 2008, didn't know it at the time. I know for a fact that there are a lot of firefighters have come down with serious cancers -- some are dying, some have died -- since Dr. Prezant's study that were not included in his study. So you know, I would love for it to be all cancers, but I don't think that we can do it based on what we've been tasked.

I do think that when we get to the second round of this, if that's where we end up, and we have to look at biologic plausibility versus strongest evidence, I think biologic plausibility is the key. And I think, you know, there are cancers that need to be included when we get there -- brain cancer and pancreatic cancer, for sure. And maybe we can move on to that, but reluctantly I have to say no.

MS. FLYNN: This is Kimberly, and I'd like to just raise I guess a point of clarification, refer to the testimony of Dr. Melius. Yes, cancer -- we accept that cancer is a multifactorial disease. But there are many checks and balances. Once the STAC makes the recommendation, the implementation of that recommendation is going to mean that the physician of each patient has to attribute the cancer to World Trade Center -- well, first of all there's the diagnosis of the cancer, and then there is the attribution of the cancer. And that physician will of course be taking into account the

3435

whole history of exposure to World Trade Center in detail. So I -- you know, it's not the case that we should be kind of making that decision out in advance by saying 'Well, you know, certain cancers there's some evidence for but it's just not quite enough for us to add those cancers to the list.' And there are steps of scientific and medical evaluation down the line before anyone is accepted for treatment or anyone's treatment is covered.

DR. WARD: This is Liz. I did want to make a comment about that and I'm hoping that some of the Committee members who have occupational medicine and clinical experience will comment on it as well, 'cause from my point of view as an epidemiologist for those cancers that don't have, you know, a substantial body of evidence supporting their potential association I would be hardpressed -- I mean I'm not sure how a physician would make that determination about those cancers. I mean it's not in our immediate, you know -- I mean we're not -- that's not exactly what we're talking about here but I think it's relevant because it -- you know, if there's no -- if there's very little evidence associating that cancer potentially with the exposures, then there's very little rationale or criteria to determine that one person's -- one person's cancer is World Trade Center-related and the other's isn't. So would any of the occupational physicians or practicing physicians like to comment on that?

(No response)

**DR. WARD:** All right. Well, with no further comments on that, we'll open the floor for the next speaker.

(No response)

**DR. WARD:** Is everyone still there? **UNIDENTIFIED:** Yes, we're all still here.

MS. SIDEL: Well, I actually have a question. Maybe Paul can help.

**DR. WARD:** Sure, go ahead.

**MS. SIDEL:** Okay. Is there a safeguard with -- in place, going forward so if Dr. Howard -- when he was speaking, we meet at his pleasure and we answer this question for him, and so until he has another big question, we're sort of, you know, on call. Well, how

1 would we raise these issues if -- say new evidence becomes 2 available if everything is -- I'm just remembering that there's only 3 four years for this, or five years, for this whole Committee, how 4 could these -- how could issues for things that we don't have the 5 kind of evidence that we want to have -- when that evidence becomes available, or is there some way that we can do research to 6 7 get the evidence? 8 **DR. MIDDENDORF:** Well, what would happen is if someone were to 9 petition the Administrator again to add cancer or a specific type of 10 cancer or another health condition, he then could come back to the 11 Committee and ask for the Committee's advice on it. 12 MS. SIDEL: I see. Okay. Thank you. 13 DR. WARD: What I'd like to do then is make sure -- see if there's 14 anyone else who'd like to speak either in favor of the motion or 15 against the motion. And if not, call for a vote. **DR. MIDDENDORF:** Okay. I'd like to make sure that the motion is 16 17 stated as the Committee wants it. 18 **MS. FLYNN:** So right now it's possible -- I'm sorry, this is Kimberly. 19 Is it possible for me to -- and I don't know my Robert's Rules all 20 that well, but to make a friendly amendment, citing a 21 precautionary principle as a scientific basis to include cancers that 22 are not listed under option two? The point being, you know, that --23 DR. MIDDENDORF: What I would need is wording here. How 24 would --25 MS. FLYNN: You would need wording. 26 DR. MIDDENDORF: Well, how would you word your proposed 27 amendment? 28 MS. FLYNN: What is the original -- could I ask you please to repeat 29 the original --30 **DR. MIDDENDORF:** The motion on the table is 'The Committee 31 recommends that all cancers be covered.' 32 MS. MEJIA: Hi, this is Guille. Just want to remind everyone that as 33 the maker of the motion I think I'm the one that has to accept the 34 amendment --35 MS. FLYNN: Yes, you are.

| 1  | MS. MEJIA: to the motion.   |
|----|---|
| 2  | MS. FLYNN: Yes.   |
| 3  | DR. MIDDENDORF: So what would the amendment be?                       |
| 4  | MS. FLYNN: I moved that any cancers not covered under option          |
| 5  | two would be covered under option one, under the precautionary        |
| 6  | principle.  |
| 7  | MS. DABAS: Hi, this is Valerie. Kimberly, is it possible that we get  |
| 8  | a clean vote on this, just, you know, the first one, which was what   |
| 9  | Guille said?  |
| 10 | MS. FLYNN: Yes, I'll withdraw I'll withdraw the amendment.            |
| 11 | MS. MEJIA: Thank you.   |
| 12 | <b>DR. WARD:</b> Okay, so it's the motion has been called for a vote. |
| 13 | Paul, do you want to do the   |
| 14 | DR. MIDDENDORF: Sure, I'll do an alphabetical voting.                 |
| 15 | Tom Aldrich?  |
| 16 | DR. ALDRICH: I vote against this motion.                              |
| 17 | DR. MIDDENDORF: Okay, vote no. Steve Cassidy?                         |
| 18 | (No response)   |
| 19 | DR. MIDDENDORF: Steve? You're not coming through if you're            |
| 20 | speaking.   |
| 21 | (No response)   |
| 22 | DR. MIDDENDORF: Steve?  |
| 23 | (No response)   |
| 24 | DR. MIDDENDORF: I can't hear Steve so I'm going to go on to           |
| 25 | Valerie Dabas?  |
| 26 | MS. DABAS: I vote for.  |
| 27 | DR. MIDDENDORF: Vote yes. John Dement?                                |
| 28 | DR. DEMENT: No.   |
| 29 | DR. MIDDENDORF: Kimberly Flynn?                                       |
| 30 | MS. FLYNN: Yes.   |
| 31 | DR. MIDDENDORF: Bob Harrison?   |
| 32 | DR. HARRISON: No.   |
| 33 | DR. MIDDENDORF: Catherine Hughes?                                     |
| 34 | (No response)   |
| 35 | DR. MIDDENDORF: Catherine?  |
|    |   |

| 1                    | MS. HUGHES: I'm back, please.  |
|----------------------|--|
| 2                    | DR. MIDDENDORF: You're yes or no?                                      |
| 3                    | MS. HUGHES: If we vote this down, can we add cancers under             |
| 4                    | option two?  |
| 5                    | DR. MIDDENDORF: Yeah, I mean there's nothing that says that            |
| 6                    | MS. HUGHES: Well we can cover that today, is there                     |
| 7                    | DR. MIDDENDORF: Yeah, that can still be done.                          |
| 8                    | MS. HUGHES: It still can be done, because it seems that brain,         |
| 9                    | thyroid and breast are   |
| 10                   | <b>DR. MIDDENDORF:</b> We're past discussion at this point, Catherine. |
| 11                   | We need to move on. Vote yes or no.                                    |
| 12                   | MS. HUGHES: No.  |
| 13                   | DR. MIDDENDORF: I'm sorry?   |
| 13                   | MS. HUGHES: No.  |
| 15                   | DR. MIDDENDORF: Thank you. Steve Markowitz is not here.                |
| 16                   | Guille?  |
| 17                   | MS. MEJIA: No.   |
| 18                   | DR. MIDDENDORF: Carol is not here. Julia?                              |
| 19                   |  |
| 20                   | DR. QUINT: No.   |
| 20                   | DR. MIDDENDORF: Bill Rom? DR. ROM: No.                                 |
| 22                   |  |
| 23                   | DR. MIDDENDORF: Susan Sidel?  MS. SIDEL: No.                           |
| 24                   | DR. MIDDENDORF: Glenn Talaska?   |
| 2 <del>4</del><br>25 | DR. TALASKA: No.   |
|                      |  |
| 26                   | DR. MIDDENDORF: Leo Trasande?  |
| 27                   | (No response)  |
| 28                   | DR. MIDDENDORF: Leo?   |
| 29                   | (No response)  |
| 30                   | DR. MIDDENDORF: Virginia Weaver?                                       |
| 31                   | DR. WEAVER: Yeah, I just had some audio difficulties. I was calling    |
| 32                   | in on the line where I was not able to speak.                          |
| 33                   | DR. MIDDENDORF: Okay.  |
| 34                   | <b>DR. WEAVER:</b> So we're now voting for or against option one. Is   |
| 35                   | that correct?  |

1 **DR. MIDDENDORF:** That is correct, and motion one is'The 2 Committee recommends that all cancers be covered.' 3 **DR. WEAVER:** Okay. So just so -- for the record, I've been on the 4 call the entire time --5 **DR. MIDDENDORF:** Okay. DR. WEAVER: -- and have not heard the vote so far, but I would 6 7 vote against that motion. 8 **DR. MIDDENDORF:** Okay. I'm going to go back to Steve Cassidy. 9 Steve, are you on? 10 (No response) 11 **DR. MIDDENDORF:** I can't hear anything from Steve. 12 And Leo Trasande? 13 (No response) 14 **DR. MIDDENDORF:** And make sure you're not on mute. 15 (No response) **DR. MIDDENDORF:** Okay. Liz Ward? 16 17 DR. WARD: I would vote no. 18 **DR. MIDDENDORF:** Okay. Of those voting I have ten nos and one, 19 two, three -- three yes. 20 So it's back to you, Liz. 21 **DR. WARD:** All right. So for the next option -- we need a motion --22 there's a couple of motions that could be made. One would be to 23 discuss each organ site or grouping of sites individually. The other 24 could be to accept all of the sites that are currently listed, and I 25 guess in either case we can also make separate motions to add 26 addi-- for additional sites. But I guess probably the most efficient 27 way to do it would be to talk about -- for someone to make a 28 motion -- well, I guess -- why doesn't someone make a motion as to 29 how to proceed on option two? 30 MR. FLANIGAN: Can I speak? DR. WARD: Yeah. 31 32 MR. FLANIGAN: Hi, my name is Shawn Flanigan. Something that 33 wasn't mentioned, the sarcomas or bone cancers -- okay? And I 34 know that there was a lot of speaker earlier on scientific data --35 **DR. WARD:** Excuse me, Mr. Flanigan, are you a member of the

| 1  | Scientific and Technical Advisory Committee?                         |
|----|--|
| 2  | MR. FLANIGAN: No.  |
| 3  | DR. MIDDENDORF: Okay, this part of the meeting is not open to        |
| 4  | you, sir.  |
| 5  | MR. FLANIGAN: All right.   |
| 6  | DR. MIDDENDORF: Please go to mute.                                   |
| 7  | MR. FLANIGAN: Thank you.   |
| 8  | DR. WARD: Okay. Is there anyone on the Committee who would           |
| 9  | like to make a motion?   |
| 10 | MS. DABAS: Hi, it's Valerie. I make a motion for the second          |
| 11 | option, but to include breast, pancreatic and brain cancer.          |
| 12 | DR. TALASKA: Glenn Talaska. Are you going to entertain multiple      |
| 13 | options or just one at a time?                                       |
| 14 | DR. WARD: Paul, what's your recommendation on that?                  |
| 15 | DR. MIDDENDORF: Why don't you I think what might be helpful          |
| 16 | is if the Committee discussed how it really wants to proceed,        |
| 17 | whether or not it wants to go down the road of looking at            |
| 18 | everything all combined or if it would rather try to split this up.  |
| 19 | DR. TALASKA: Could we do it in this fashion? Could we if there       |
| 20 | are anyone has any objections to any of the specific cancers that    |
| 21 | are cited in the in option two thus far, why don't we bring them     |
| 22 | up and then we could have a section where we add cancers?            |
| 23 | MS. DABAS: Hi, this is Valerie again. I think there is a motion on   |
| 24 | the floor currently.   |
| 25 | UNIDENTIFIED: I agree with you, Val.                                 |
| 26 | DR. WARD: Okay, so the motion as I understand it that's on the       |
| 27 | floor is to include all of the all of the cancers and organ groups   |
| 28 | currently listed in option two, and in addition to include breast    |
| 29 | cancer, pancreatic cancer and brain cancer. Is there a second for    |
| 30 | that motion?   |
| 31 | MS. FLYNN: Kimberly, I second.                                       |
| 32 | DR. WARD: Okay. So I think we'll have discussion on that motion      |
| 33 | and then a vote. If it does not carry, then we can see if we want to |
| 34 | adopt Glenn's suggestion. Let's have discussion on that on that      |
| 35 | motion.  |

1 **DR. ALDRICH:** This is Tom Aldrich. Can I say a word? 2 DR. WARD: Sure. 3 **DR. ALDRICH:** I think the discussion we had on option one pretty 4 much informs the result of this motion. I think the big part of the 5 reason option one did not carry was that a number of people felt that there was -- there were some cancers, some of which were 6 7 included in option two, that -- for which there is insufficient 8 evidence. It seems almost a foregone conclusion what the results 9 of this vote is and I think we should just get right to the vote. 10 **DR. WARD:** Is anyone opposed to that? 11 **UNIDENTIFIED:** I think it's good. 12 **DR. WARD:** Okay, so let's proceed with the vote, Paul. 13 **DR. MIDDENDORF:** Okay. So what I've done is to copy all of the 14 bullets from motion two that are from the draft report. And then 15 also at the bottom here is 'and include breast, brain and pancreatic cancer.' The question for the Committee is how would we -- is that 16 17 sufficiently clear to what the Committee is voting on, because you 18 have a lot of ICD codes and things like that listed for the other 19 types of cancer. Does that information need to be included here? 20 Do you know specifically what you're voting on? 21 DR. WARD: My thought would be, Paul, that probably the 22 Committee has a common understanding of what we mean and 23 that if -- if we were to adopt this motion that we would then have 24 time during the remainder of the meeting to add that additional 25 information to it -- the text and the draft. 26 DR. MIDDENDORF: Okay. 27 DR. HARRISON: Liz, this is Bob Harrison. 28 DR. WARD: Yes. 29 DR. HARRISON: Those are three separate cancers, as I understand 30 it, that we're being asked to vote on as a group. Yet some 31 Committee members, including myself, may vote differently for 32 each one of those three sites. 33 **DR. WARD:** Well, I think that's okay because I think this particular 34 motion is -- well, I guess -- in the end of the day this particular 35 motion is basically saying we include all the sites that were listed

| 1  | under option two plus these three sites. And if this mot you           |
|----|--|
| 2  | know, so if this motion carries, it's true, if that's your only I mean |
| 3  | I guess the quest  |
| 4  | DR. HARRISON: Okay, I no, I understand the motion on the               |
| 5  | table.   |
| 6  | DR. WARD: If it doesn't carry then we'd have the option of looking     |
| 7  | at each site each site or group that was listed, plus each of these    |
| 8  | three sites individually.  |
| 9  | DR. HARRISON: Thank you for clarifying that.                           |
| 10 | DR. WARD: So with that, I guess we're ready for the vote, Paul.        |
| 11 | DR. MIDDENDORF: Okay. For motion two, again we'll go                   |
| 12 | alphabetically with the Chair voting last. Tom Aldrich?                |
| 13 | DR. ALDRICH: No.   |
| 14 | DR. MIDDENDORF: Steve Cassidy?   |
| 15 | MR. CASSIDY: Yes.  |
| 16 | DR. MIDDENDORF: Valerie Dabas?   |
| 17 | MS. DABAS: Yes.  |
| 18 | DR. MIDDENDORF: John Dement?   |
| 19 | DR. DEMENT: No.  |
| 20 | DR. MIDDENDORF: Kimberly Flynn?  |
| 21 | MS. FLYNN: Yes.  |
| 22 | DR. MIDDENDORF: Bob Harrison?  |
| 23 | DR. HARRISON: No.  |
| 24 | DR. MIDDENDORF: Catherine Hughes?                                      |
| 25 | (No response)  |
| 26 | DR. MIDDENDORF: Catherine, are you on?                                 |
| 27 | MS. HUGHES: Yes, thank you.  |
| 28 | DR. MIDDENDORF: Are you what is your vote?                             |
| 29 | MS. HUGHES: Yes.   |
| 30 | DR. MIDDENDORF: Okay. Steve Markowitz is not here. Guille              |
| 31 | Mejia?   |
| 32 | MS. MEJIA: Yes.  |
| 33 | DR. MIDDENDORF: And you're voting yes. Okay. Carol North is            |
| 34 | not here. Julia Quint?   |
| 35 | (No response)  |
|    |  |

1 DR. MIDDENDORF: Julia? 2 DR. QUINT: No. 3 **DR. MIDDENDORF:** No, okay. Bill Rom? 4 DR. ROM: No. 5 **DR. MIDDENDORF:** Susan Sidel? MS. SIDEL: Yes. 6 7 DR. MIDDENDORF: Glenn Talaska? 8 DR. TALASKA: No. 9 **DR. MIDDENDORF:** Leo Trasande? 10 (No response) 11 **DR. MIDDENDORF:** Virginia Weaver? 12 DR. WEAVER: No. 13 DR. MIDDENDORF: Liz Ward? 14 DR. WARD: No. 15 **DR. MIDDENDORF:** Okay. I have -- of those voting, eight voted no, 16 six voted yes, so the motion does not carry. 17 **DR. WARD:** One procedural question 'cause Steve Cassidy was back 18 on the phone for this vote. Steve, did you attempt to vote on the 19 first motion? 'Cause I think we didn't hear you. MR. CASSIDY: I did vote on the first motion. I voted reluctantly 20 21 no. 22 **DR. WARD:** Okay. 23 MR. CASSIDY: The first option you mean, right? 24 DR. WARD: Yeah, yeah. 25 **DR. MIDDENDORF:** I will go back -- initially I had you as not voting. 26 I will put you down as a no then. 27 MR. CASSIDY: I must have -- I gave a nice speech, you must have 28 missed it. I must have been muted. 29 **DR. MIDDENDORF:** No, it's just when we went to the roll call vote, 30 you didn't come in on it, so... 31 DR. WARD: Yeah, I'm hoping we're not having -- you know, missing 32 people on votes because of technical difficulties, so I guess we'll --33 we will go back and check on those who were missing from the 34 second voting -- voting round, just to make sure we didn't -- we didn't miss their vote because we couldn't hear them. 35

1 Okay. So then I think the next logical step might be to proceed the 2 way Glenn suggested, just to have a -- you know, an initial 3 discussion and ask for people to speak on those cancer sites that 4 they're opposed to including on that original list, or cancer sites 5 that they would like to see added. Why don't we do the ones that people are opposed to including from the original list first, just to 6 7 keep everything organized -- so the floor is open. 8 **DR. ALDRICH:** This is Tom Aldrich. I oppose the inclusion of 9 prostate cancer for the reasons that are discussed in -- I think it's 10 the second paragraph about prostate cancer. 11 **DR. WARD:** Okay, thank you. Now Paul, I think I just might have 12 made a procedural error. Do we need a formal motion to open the 13 floor for a discussion on the --14 **DR. MIDDENDORF:** I think we need a motion that people will be 15 discussing; something very specific. 16 **UNIDENTIFIED:** Yeah, I think at some point we can just move that 17 certain -- whether we agree, so -- or we could have -- Tom could 18 make a motion, and if no one seconded it, then it would die, for 19 example. And then if not, then we could have -- so if someone 20 suggests that one cancer be removed, we could have a second on 21 that motion to remove it, and then if not, then that motion to 22 remove it would die and then we could go on to a discussion and 23 vote on whether that specific cancer should be removed. We could 24 go one by one if we wanted. 25 **DR. MIDDENDORF:** Yeah, another potential for the Committee to 26 consider is whether or not it wants to go through the bullets that 27 were in -- individual bullets and just do those. So at some point 28 you will come up with something you don't want to include and you 29 can make a motion to -- to pull them out. 30 **UNIDENTIFIED:** Bullets where? I'm sorry. 31 **DR. MIDDENDORF:** From the report, the draft report. 32 **UNIDENTIFIED:** Okay, but I was just looking for where we had it. 33 **DR. MIDDENDORF:** In option two. **UNIDENTIFIED:** Okay, hold on. 34 35 **DR. WARD:** I mean one way to do that might be to find out -- like if

1 we go to the first bullet we might say 'Is anyone opposed to 2 including -- including (indiscernible) neoplasms of the respiratory 3 system' or wish to propose that specific cancers within that 4 grouping be excluded. And then if not, we can just go -- we don't 5 really need discussion. We can go for the vote. DR. ALDRICH: That makes really good sense. We could group the 6 7 vote. 8 MS. DABAS: Do we sort of know that there are going to be a 9 couple of problems, and maybe we could just go to those? 10 DR. WARD: Well, I think that was what Glenn was proposing, and I 11 guess either way is fine. It seems that we probably will want --12 since we're including these -- since we're considering these 13 individually, I think we'll probably want a vote on the record anyway, so it might be just as efficient to go through them one by 14 15 one, have the vote, if they're -- I mean find out if there's anyone 16 who wants to speak against it or modify it and then let's go to the 17 vote. 18 **DR. HARRISON:** Yeah, I think particular cancers -- I mean most of 19 us are going to agree with most of the ones on the list, perhaps. At 20 least that would be my surmise. To go over each one and to vote 21 to include each one is not -- you know, our report includes them 22 already. We just -- I think it would be more efficient if we just 23 voted to remove particular ones. 24 **DR. MIDDENDORF:** This is (indiscernible). I think you need to 25 move -- or make motions to include and/or exclude. It needs to be 26 on the record in both directions. 27 MS. HUGHES: Catherine Hughes here. On prostate cancer I 28 understand the Veterans Affairs for Agent Orange does include 29 prostate cancer, and some of the chemicals that were in Agent 30 Orange were down at the World Trade Center as well -- point of 31 clarification. 32 MR. CASSIDY: Liz, Steve Cassidy. 33 **DR. WARD:** Yes, Steve. MR. CASSIDY: My thought was -- I mean that was a very close 34 35 vote, eight no, six yes. I mean maybe -- maybe there's a consensus

| 1  | or maybe there's a theme emerging among the eight nos that to        |
|----|--|
| 2  | be fleshed out, which would make this an easier process to have a    |
| 3  | second vote. I don't know if there's                                 |
| 4  | DR. WARD: That's fine. I mean what we can do is I guess we can       |
| 5  | talk about we can make a motion to proceed that way, and then        |
| 6  | if we need the formality of a vote on each and every one, we can     |
| 7  | do that.   |
| 8  | DR. ROM: Liz, this is Bill Rom. I would like to second Tom Aldrich's |
| 9  | motion that the entire second list be accepted, with the exception   |
| 10 | of prostate cancer, and have a vote.                                 |
| 11 | DR. WARD: Shall we so that's the formal motion, Paul, so we          |
| 12 | take a vote on shall we proceed on that motion?                      |
| 13 | DR. MIDDENDORF: This motion does not include breast, brain or        |
| 14 | pancreatic. Is that correct?   |
| 15 | DR. ROM: That's correct.   |
| 16 | DR. MIDDENDORF: Let me pull all this down and I will find            |
| 17 | DR. WARD: But it doesn't close the it doesn't close the option of    |
| 18 | discussing brain, breast   |
| 19 | DR. MIDDENDORF: No, it's just that they aren't included in this      |
| 20 | particular one.  |
| 21 | DR. WARD: Right.   |
| 22 | DR. MIDDENDORF: I'm looking for the bullet on prostate.              |
| 23 | DR. ALDRICH: It's page six, starts on line 26, I think.              |
| 24 | DR. MIDDENDORF: Okay, here it is, 'Committee recommends              |
| 25 | prostate' so it comes down to here. Is it Liz, do you want to look   |
| 26 | or who made the motion?  |
| 27 | DR. ALDRICH: That was me, Tom.                                       |
| 28 | DR. MIDDENDORF: Tom, do you want to check and make sure that         |
| 29 | I've highlighted the part you want me to remove?                     |
| 30 | DR. ALDRICH: Yes.  |
| 31 | DR. MIDDENDORF: It is the correct section?                           |
| 32 | DR. ALDRICH: Yes, it is.   |
| 33 | DR. MIDDENDORF: (Unintelligible)                                     |
| 34 | DR. ALDRICH: I had another change that I'd like to recommend. Is     |
| 35 | this the time to do it or not?                                       |

1 **DR. MIDDENDORF:** Yeah, I think you can amend your own motion, 2 3 **DR. ALDRICH:** Well, regarding the cancers of the eye -- let me find 4 out where that is again -- oh, it's page seven, line 16, cancers of the 5 eye and the orbit be listed for individuals engaged in welding. You know, World Trade Center exposure was notable for a tremendous 6 7 volume of eye irritation, such that emergency treatment of --8 washing out the eyes was the most common emergency treatment 9 that was provided acutely, and it was far more than welders. So I 10 think it would be a reasonable extrapolation to say that, with the 11 amount of foreign bodies present in the eyes of World Trade 12 Center responders, and probably residents, it ought not to be 13 limited to welders. 14 DR. WARD: So we could just drag the language -- end at 'World 15 Trade Center-related condition' and strike the --**DR. ALDRICH:** That's what I would recommend. 16 MS. HUGHES: Catherine, Catherine seconds it. 17 18 MR. CASSIDY: Did -- did -- was that a formal motion, that we --19 MS. HUGHES: It's a formal motion. 20 MR. CASSIDY: -- that we take that -- no, he has to make that as a 21 formal motion. 22 **DR. ALDRICH:** Yes, well, I would if I'm allowed to. 23 MR. CASSIDY: Okay. And would you add it to your other one is 24 what I'm asking. 25 **DR. ALDRICH:** If I'm allowed to. 26 MR. CASSIDY: Okay. So both those changes. 27 I second it, too. 28 **DR. MIDDENDORF:** The motion on the table is for this 'engaged in 29 welding.' 30 DR. ALDRICH: You can get rid of everything after 'condition.' 31 DR. WARD: Right. 32 DR. MIDDENDORF: After 'condition', okay. Okay, you want the 33 next sentence struck as well? 34 DR. ALDRICH: Yes. 35 **DR. MIDDENDORF:** So is that the way you want it to read, 'The

1 Committee recommends that cancer of the eye and orbit be listed 2 as a WTC-related condition'? 3 **DR. ALDRICH:** Yes, but the next -- then there should be a carriage 4 return. 5 **DR. MIDDENDORF:** Got it, okay. **DR. WARD:** So if the Committee votes in favor of this motion, we 6 7 may need to add a sentence there regarding the rationale, but we 8 can go ahead and vote because -- I mean I think -- the rationale 9 was stated, but I don't think it was captured, so we'll have to 10 capture it. 11 MS. HUGHES: Liz, Catherine Hughes here. As a former -- I used to 12 do construction way back when. Typically you're supposed to have 13 shields around to protect where welding is, so even if you're not 14 actually doing the welding you can also be exposed, and there was 15 intense dust and smoke in the air for months. 16 DR. WARD: All right. 17 DR. HARRISON: So Liz, this is Bob. Just so I understand, the 18 proposal on the table is to eliminate the connection to welding and 19 list it just as cancer of the eye and orbit. 20 **DR. WARD:** Right, and the rationale would be that the eye was of -21 - you know, the irritation of the eye was a frequent event among 22 people who were working at the site, so the rationale is that -- you 23 know, that the direct contact with the materials was causing 24 irritation. The original ration--25 **UNIDENTIFIED:** Would somebody on the call be able to speak to 26 the scientific or epidemiological evidence regarding cancer of the 27 eye and orbit relative to irritants, as opposed to welding? I don't 28 know this literature. 29 DR. WARD: Yeah, and the welding really came from the IARC 30 determination, so the -- so in the IARC compilation of cancer 31 science related to specific exposures, eye was specifically called 32 out for welding and not for anything else. I mean -- but I think the 33 rationale could be along the lines -- I think somewhere in here 34 where we talked about lip cancer -- I -- yeah, I think the lip on pa--35 on my updated draft is bottom of page five, but we basically --

1 since lip, oral cavity and pharynx have not been specifically 2 designated in any of the sources, but because it's connected to all 3 the other -- you know, upper respiratory tract and the digestive 4 tract -- the rationale was that the lip, oral cavity and pharynx have 5 a high potential for direct exposure to toxic materials through hand-to-mouth contact. And we've already included skin cancer, so 6 7 the eye is another, you know, surface on the body where you 8 would expect that there would be direct contact with toxins. 9 **DR. ALDRICH:** Where we know there was direct contact, because 10 there is literature about numbers of people who required eye 11 irrigation. 12 DR. WARD: Right. 13 **DR. HARRISON:** This is Bob. Just a follow-up question. Is there 14 anything in the rationale -- and this would probably mean going 15 back to the IARC document to understand why they listed welding, that's specific to welding fumes as opposed to other irritants that 16 17 would have been present at -- or were present at Ground Zero? 18 **DR. WARD:** Not to -- I mean I -- yeah, I did not look at that source 19 document from IARC for that specific exposure. 20 **DR. DEMENT:** Hi, Liz, this is John Dement. I think the issue with 21 IARC is simply they were reviewing welding as an exposure 22 generally, and looking at sites where cancers were increased. So in 23 addition to eye, the document talks about lung and some other 24 sites. 25 DR. HARRISON: John, this is Bob. So there were no other -- so it 26 was a epidemiological observation, not specifically linked to some 27 exposure? 28 DR. DEMENT: No, it's --29 **DR. HARRISON:** In the IARC review. 30 DR. DEMENT: Yeah, yeah, you know, IARC reviews typically --31 exposures that they review some --32 **DR. MIDDENDORF:** Hang on for just a second. For the purposes of 33 the transcript and the record, it would be helpful if people would 34 identify themselves before just jumping in. 35 **DR. HARRISON:** That was Bob Harrison making a comment and that

1 -- I think that was John Dement responding. 2 **DR. WARD:** I also think that I -- I mean I am in favor of keeping it in 3 with the rationale, but I also think that eye and orbit is such a rare 4 site, so we're going to -- I mean it will -- it would -- if we vote to 5 include the rare cancers, I think it will probably -- would be included for that reason as well. 6 7 DR. ALDRICH: Well, I think that -- this is Tom Aldrich. I think there's more specific, admittedly indirect extrapolative evidence 8 9 for eye cancers to be expected than for other rare cancers --10 DR. WARD: Yeah, yeah. 11 **DR. ALDRICH:** -- but it's fully speculative. 12 **DR. WARD:** Yeah, yeah. So I guess the gues-- so -- so to the folks 13 who are questioning whether -- what the specific mechanism or the 14 specific agent would be, do you feel like you have enough 15 information to vote on the motion, or do -- or -- how should we 16 proceed? 17 DR. HARRISON: Yeah, this is Bob Harrison. I -- Liz, I confess I 18 simply don't have enough information. Eye cancers are extremely 19 rare. I don't think I've ever encountered a case in my 30 years of 20 occupational medicine practice, and there's certainly biological 21 plausibility to think that if IARC was to (indiscernible) for welding --22 for welders, that a mechanism would be irritation. But I just don't 23 know beyond welding whether there's any other toxicologic or 24 scientific literature that would support eliminating the clause. I 25 just simply confess I -- I have insufficient information. 26 DR. WARD: Okay. 27 MR. CASSIDY: This is Steve Cassidy. Can I just say something? 28 **DR. HARRISON:** Yeah. 29 MR. CASSIDY: Somebody -- somebody earlier, I don't know who, 30 talked about the -- I think it was Tom -- talked about the number of 31 people who are -- who are recorded as having their eyes cleaned 32 and washed. And having been there, I can tell you that the Red 33 Cross and other volunteers were there every day washing the eyes 34 of first responders. I would say that virtually every first responder 35 who was there needed to have his eyes irrigated day after day after

day. So I don't know if there's any data out there that talks about people having dust in their eyes for 30 or 60 days, over a 90 or 120day period, so maybe there is no study that we can compare this event to, but -- but I know that irritants cause cancer, and that people's eyes were irritated at a level probably never before seen, on an ongoing basis -- not a one-time, not one day, ongoing. DR. MIDDENDORF: This is Paul. Just something that you may want to think about is that welding -- many forms of welding can generate ultraviolet light, which is an ionizing form of radiation. **UNIDENTIFIED:** May I say something also as a point of what Steve just said? I just want to say that our supply tent went through boxes full of cases of saline solution and we didn't -- I mean I think we were just using the kind of saline solution that you use for contact lenses, and we were just constantly running out. It was -people just -- we just went through it, like tons of it. I know that's not very scientific, but it was just always used every day for as long as I was down there, which was three months. Thanks. MS. HUGHES: Catherine Hughes here. I also just learned that

**DR. HARRISON:** Liz, may -- this is Bob Harrison. May I be recognized?

there were wash basins at the edge of the Pile that were used

DR. WARD: Sure.

regularly to clean the eyes, as well.

DR. HARRISON: Thank you. Do we have a mechanism, as part of the Committee process today, to -- you know, to place issues like this on a -- in a so-called parking lot, or issues that we recognize, as a Committee, are a potential concern or a possible -- possibly for listing, but that need further information or research or data? This is -- I don't know where this will come up in additional discussions. DR. WARD: Well, I think that where we are now is that we have a motion on the floor and we have a second to the motion, and we have an amendment that was proposed and was accepted by the person who made the original motion. So I think what we would need to do is call for a vote, see what the vote is and then -- you know, it's not -- you know, again, we can put anything in the

| 1  | parking lot, but unless John Howard chooses to take it out of the   |
|----|---|
| 2  | parking lot, it's you know, I but I do think we should go ahead     |
| 3  | and have a vote on the motion that was proposed, as amended         |
| 4  | as Paul has captured it. Paul?                                      |
| 5  | DR. MIDDENDORF: Yes. So the motion on the table now includes        |
| 6  | all of option two, except for prostate, and removes welding from    |
| 7  | the discussion of the eye. It does not include breast, brain or     |
| 8  | pancreas pancreatic cancer. Is that correct? Is that the motion     |
| 9  | that you have, Tom?   |
| 10 | DR. ALDRICH: Yes, it is.  |
| 11 | DR. MIDDENDORF: Let's go ahead and take the vote then.              |
| 12 | UNIDENTIFIED: I have a question.                                    |
| 13 | DR. MIDDENDORF: Tom Aldrich?  |
| 14 | MR. CASSIDY: I have one question Steve Cassidy. Can I ask a         |
| 15 | question before the vote?   |
| 16 | DR. MIDDENDORF: Yes.  |
| 17 | MR. CASSIDY: Okay. If we vote yes, does that mean this is the       |
| 18 | final, or are there other people able to make motions to add things |
| 19 | to this particular motion? I mean is this the final?                |
| 20 | DR. WARD: No. Well, I think the idea was we vote on this, and       |
| 21 | then we have the opportunity to make motions to add additional      |
| 22 | things.   |
| 23 | MR. CASSIDY: Okay. Thank you.                                       |
| 24 | DR. MIDDENDORF: So voting on motion three, which is all of          |
| 25 | option two except prostate, and amending the discussion of the      |
| 26 | eye to remove welding, and does not include breast, brain or        |
| 27 | pancreas pancreatic cancer. So Tom Aldrich?                         |
| 28 | DR. ALDRICH: I vote yes.  |
| 29 | DR. MIDDENDORF: Steve Cassidy?                                      |
| 30 | MR. CASSIDY: Yes.   |
| 31 | DR. MIDDENDORF: Valerie Dabas?                                      |
| 32 | MS. DABAS: Yes.   |
| 33 | DR. MIDDENDORF: John Dement?  |
| 34 | DR. DEMENT: Yes.  |
| 35 | DR. MIDDENDORF: Kimberly Flynn?                                     |

| 1  | MS. FLYNN: Yes.   |
|----|---|
| 2  | DR. MIDDENDORF: Bob Harrison?                                   |
| 3  | DR. HARRISON: Yes.  |
| 4  | DR. MIDDENDORF: Catherine Hughes?                               |
| 5  | MS. HUGHES: Yes.  |
| 6  | DR. MIDDENDORF: Steve Markowitz is not here. Guille?            |
| 7  | MS. MEJIA: Yes.   |
| 8  | DR. MIDDENDORF: Carol is not here. Julia?                       |
| 9  | DR. QUINT: Yes.   |
| 10 | DR. MIDDENDORF: Bill?   |
| 11 | DR. ROM: Yes.   |
| 12 | DR. MIDDENDORF: I'd better start using last names again. Susan  |
| 13 | Sidel?  |
| 14 | MS. SIDEL: Yes.   |
| 15 | DR. MIDDENDORF: Glenn Talaska?                                  |
| 16 | DR. TALASKA: Yes.   |
| 17 | DR. MIDDENDORF: Leo Trasande?                                   |
| 18 | (No response)   |
| 19 | DR. MIDDENDORF: Virginia Weaver?                                |
| 20 | DR. WEAVER: Yes.  |
| 21 | DR. MIDDENDORF: Liz Ward?                                       |
| 22 | DR. WARD: Yes.  |
| 23 | DR. MIDDENDORF: Well, that sounds like it carries unanimously   |
| 24 | from those who voted 14 yes and zero no.                        |
| 25 | DR. WARD: Okay, so now we'll entertain motions on really        |
| 26 | anything people want, including cancers that are proposed to be |
| 27 | added.  |
| 28 | One question, Paul. Should we go ahead and take the scheduled   |
| 29 | break?  |
| 30 | DR. MIDDENDORF: I think that would be a good idea, give         |
| 31 | everybody a chance to   |
| 32 | DR. WARD: Think.  |
| 33 | DR. MIDDENDORF: break or whatever they need to do.              |
| 34 | DR. WARD: Yeah, great. Okay, so                                 |
| 35 | DR. MIDDENDORF: That's for all of you for ten minutes.          |
|    |   |

1 **UNIDENTIFIED:** Liz, before we take a break, just one quick 2 question. Are we going to be able to return to say the letter and 3 the document for minor edits? 4 DR. WARD: I would hope so. I mean I -- I think first we should 5 wrap up the major issues, and then go through the more minor 6 ones. 7 DR. QUINT: Liz, this is Julia. What about factual errors, 'cause I 8 have... DR. WARD: Well, I don't -- I guess if they're significant, let's 9 10 discuss them on the call. If they're minor, send the corrections to 11 me and I'll make them in the document. 12 DR. QUINT: Okay, I --13 **DR. MIDDENDORF:** Make sure you send anything to me that you 14 send to Liz. 15 DR. QUINT: Absolutely. I don't know what you -- how you 16 distinguish that, but there are some things that -- for which --17 they're incorrect, so... 18 **DR. WARD:** Okay. Well, why don't we get -- why don't we talk 19 about them then. You know, hopefully we can -- you know, maybe 20 the order of business should be let's finish, you know, the major 21 recommendations, then we'll discu-- then we'll note any factual 22 errors, and then we'll go to any more minor editing. 23 **DR. QUINT:** Okay, thanks. 24 DR. MIDDENDORF: So let's take a ten-minute break. We'll be back 25 here in ten minutes sharp. 26 (Recess taken from 3:14 p.m. to 3:24 p.m.) 27 DR. MIDDENDORF: This is Paul again. We need to get started up, 28 so if everybody will come back to the phone. 29 DR. TALASKA: Okay, Paul, Glenn's on. 30 **DR. MIDDENDORF:** I'll do a roll call here in just a second. 31 **DR. ALDRICH:** Paul, this is Tom Aldrich. Can I send you some 32 suggested wording for that eye injury thing? 33 **DR. MIDDENDORF:** You mean for the body of the report? 34 DR. ALDRICH: Yeah. 35 **DR. MIDDENDORF:** Yeah, you can send it.

| 1  | DR. ALDRICH: Thanks.   |
|----|--|
| 2  | DR. MIDDENDORF: Okay, let's do a roll call just to make sure |
| 3  | everybody's here. Tom Aldrich?                               |
| 4  | DR. ALDRICH: Here.   |
| 5  | DR. MIDDENDORF: Steve Cassidy?                               |
| 6  | MR. CASSIDY: Here.   |
| 7  | DR. MIDDENDORF: Valerie Dabas?                               |
| 8  | MS. DABAS: Here.   |
| 9  | DR. MIDDENDORF: John Dement?                                 |
| 10 | DR. DEMENT: Here.  |
| 11 | DR. MIDDENDORF: Kimberly Flynn?                              |
| 12 | MS. FLYNN: Here.   |
| 13 | DR. MIDDENDORF: Bob Harrison?                                |
| 14 | DR. HARRISON: Here.  |
| 15 | DR. MIDDENDORF: Catherine Hughes?                            |
| 16 | MS. HUGHES: Here.  |
| 17 | DR. MIDDENDORF: Steve Markowitz is not here. Guille?         |
| 18 | MS. MEJIA: Here.   |
| 19 | DR. MIDDENDORF: Carol North is not here. Julia Quint?        |
| 20 | DR. QUINT: Here.   |
| 21 | DR. MIDDENDORF: Bill Rom?                                    |
| 22 | (No response)  |
| 23 | DR. MIDDENDORF: Come back to Bill. Susan Sidel?              |
| 24 | MS. SIDEL: Here.   |
| 25 | DR. MIDDENDORF: Glenn Talaska?                               |
| 26 | DR. TALASKA: Here.   |
| 27 | DR. MIDDENDORF: Leo Trasande?                                |
| 28 | (No response)  |
| 29 | DR. MIDDENDORF: Okay. Liz Ward?                              |
| 30 | DR. WARD: Here.  |
| 31 | DR. MIDDENDORF: Virginia Weaver?                             |
| 32 | DR. WEAVER: Here.  |
| 33 | DR. MIDDENDORF: Okay. Bill Rom, are you on yet?              |
| 34 | DR. ROM: Here.   |
| 35 | DR. MIDDENDORF: Okay, great. Okay, back to you, Liz.         |
|    |  |

1 DR. WARD: Okay, the floor's open for motions regarding changes 2 or additions to the recommendations under option two. 3 (No response) 4 **DR. WARD:** Okay, so just to be clear, this is the opportunity to 5 suggest adding additional cancers such as breast, pancreatic and brain. 6 7 **DR. HARRISON:** Liz, this is Bob Harrison. 8 DR. WARD: Yes. 9 DR. HARRISON: On page seven of what I have as the draft I 10 printed, the last bullet -- it states 'The Committee recommends 11 that lymphoma, leukemia and myeloma' and then it references 12 Appendix 1 for the site and histology codes. Do those codes 13 include both Hodgkin's and non-Hodgkin's lymphomas, or is it just 14 the non-Hodgkin's lymphomas? 15 **DR. WARD:** At this point they include Hodgkin's lymphomas, and they also include CLL, which I think Bill -- Bill has some concerns 16 17 about also. So that is something that we can discuss. Maybe --18 Paul, do we need a motion or can we just discuss it first? 19 DR. MIDDENDORF: You can have a little discussion, but if 20 somebody wants to change anything there'll have to be a motion. 21 **DR. WARD:** Right, right. 22 DR. HARRISON: Yeah, I'm not -- I wasn't quite ready to make a 23 motion, and I may -- I apologize if I'm out of Robert's Rules of 24 Order here. I just had some concerns about whether we intend to 25 include all lymphomas, both Hodgkin's and non-Hodgkin's 26 lymphomas. I think that the level of scientific evidence for 27 Hodgkin's disease or Hodgkin's lymphomas is less certain than for 28 the non-Hodgkin's lymphoma. 29 **DR. WARD:** Yeah, and I can tell you why it was done this way, is 30 that in the -- the IARC monograph program has basically lumped all 31 of these -- the leukemias and lymphomas together. And in part it's 32 based on the rationale that when you're looking at the 33 epidemiologic studies, especially the historical studies of that 34 whole group, there have been so many -- I mean some of them were based on death certificates where the classification of the 35

leukemia and lymphoma was -- was, you know, very broad. And in some cases the groupings have changed over time, so IARC kind of decided to lump all of them together because when you try to list them there's so much potential for inaccuracy. So that's -- so I kind of followed the lead of the most recent work by IARC where they were kind of tabulating cancer sites associated with IARC carcinogens and they basically put all of them together. But you know, I agree with you from what I understand, and I did double-check when, you know, you made the comment that -- you know, if -- there is very little occupational/environmental exposure that's been associated with Hodgkin's lymphoma and quite a -- you know, much more associated with NHL.

**DR. HARRISON:** Thank you, Liz. And with that explanation in terms of how this is listed, I agree with the current listing and the phrase then on page seven regarding the LACs. But I don't -- I don't have a specific motion to make to amend that.

DR. WARD: Okay.

**MS. DABAS:** Hi, Liz, this is Valerie. I wanted to make not a motion for a vote but a motion to discuss the inclusion of brain, pancreas and breast cancer. I really would kind of like to get some feedback as to why they were excluded, where are we on trying to get those included. These are three cancers that we at the PBA have seen very high amounts of.

MR. CASSIDY: This is Steve Cassidy. I'm interested in that discussion, too, and I'm not sure that when that vote was taken, and was lost eight to six, whether everybody voted no -- of the eight -- simply because all three were added, any one particular of the three, or if in fact it was the prostate cancer that was removed from option two. So I'd like to know where people stand on that also.

**DR. WARD:** Okay. Well, I'm comfortable with just opening the floor for discussion on these three cancers without yet having a formal motion, so anyone can begin.

**MS. DABAS:** This is Valerie again. I guess I would start with pancreas cancer. I think that we've included the digestive system,

and the pancreas is considered part of the digestive system as well as the endocrine system, and excluding that I think is very -- it doesn't make sense on the idea of biological plausibility where I read in some studies that they say that the inflammation also causes pancreas cancer, that certain carcinogens can interfere with the normal functions of cell growth, which is directly part of the endocrine system. So I'm a little confused about why pancreas was removed from the list -- was not on the list.

DR. WARD: Okay. Anyone else?

**UNIDENTIFIED:** Well, what are the grounds for adding it? What are the scientific grounds for adding it, other than that -- you know, we looked at the chemicals that were involved and we couldn't see chemicals where we had any sort of documentation of the exposure that were causing brain or pancreatic cancer, so I'm just wondering why -- how we would justify their inclusion and who should work on that.

DR. WARD: Who said that, you know -- I think -- I just doublechecked, and you know, in the kind of groupings that I used, which were the SEER groupings, it is correct that pancreas is listed as a digestive system cancer. I can read a -- answer it better -- I didn't -- I actually didn't include all in this list of cancers, only those that were specifically indicated by the other three sources, so -- so among the digestive (inaudible) cancers there's esophagus, stomach, small intestine -- which I didn't include; colon and rectum, anus, anal canal and anorectum -- which I didn't include; liver and intrahepatic bile duct -- which I did include. Then there's gall bladder and other biliary -- I believe I didn't include; pancreas -- which I didn't include. So it was really within the digestive tract I included those that had been specifically implicated by any of the (inaudible) sources. I also included retroperitoneum, peritoneum, omentum and mesentery because I had a feeling that those kind of overlapped with the mesothelioma, but they were kind of sites where you might find mesotheliomas so I wanted to include them with central mesotheliomas. So I guess that's the rationale that was the -- you know, within the digestive tract, only those sites

1 that have been implicated by any one of the three (indiscernible) 2 were included. 3 **UNIDENTIFIED:** So can I make a motion to consider adding 4 pancreatic to the digestive system of organs? 5 **UNIDENTIFIED:** I second. DR. WARD: Any discussion? 6 7 **DR. MIDDENDORF:** I need specific wording on the motion first. 8 **UNIDENTIFIED:** On page five, line 14, the Committee recommends 9 certain cancers of the digestive system. So under the long list of 10 esophagus, stomach, colon, rectum, liver, bile duct, da, da, da, da, 11 da, include pancreatic 'cause it's related in there. 12 **DR. ALDRICH:** This is Tom Aldrich. An important reason why all 13 those digestive tract cancers were included is because of exposure. 14 I mean direct exposure to high volume of dust because of all the 15 aspirated and swallowed material. And that doesn't get into contact with the pancreas in the same sense that it does with 16 17 esophagus and stomach and small bowel and large bowel. And I 18 think that's a really important difference, and so the quality of the 19 evidence is different for the two types of digestive cancers. 20 **UNIDENTIFIED:** I guess then I look again at, you know, the 21 inclusion of -- we can look at digestive, but we could also look at 22 the endocrine system where we've included thyroid, we've 23 included kidney, we've included stomach, and then again we're 24 excluding pancreas. You know, that's two systems where we have 25 ample amount of organs that have been included but are including 26 -- choosing to exclude an organ that is there twice, essentially. And 27 then, you know, from speaking to some -- just looking at the 28 literature it says then the pancreatic cancer is one of the cancers 29 that is very difficult to diagnose, and that might be one of the 30 reasons why it hasn't made it on the list and the liver has. 31 DR. MIDDENDORF: I'm going to butt in for just a second and 32 remind people you need to identify who is speaking so that it's on 33 the record. So this motion was made by Tom Aldrich and the 34 motion was the Committee recommends adding pancreatic cancer 35 to the list of digestive tract cancers.

| 1  | Is that the motion that's on the table?                              |
|----|--|
| 2  | DR. ALDRICH: Yeah, but it wasn't made by me.                         |
| 3  | DR. MIDDENDORF: Okay. Who was that made by?                          |
| 4  | UNIDENTIFIED: Catherine.   |
| 5  | MS. HUGHES: Catherine Hughes.  |
| 6  | DR. MIDDENDORF: Catherine, okay.                                     |
| 7  | DR. WARD: And it was seconded by Valerie?                            |
| 8  | UNIDENTIFIED: I'll take a friendly amendment to Valerie's ideas,     |
| 9  | too. Either one is fine.   |
| 10 | MS. DABAS: Yes, I would second Catherine's motion to add             |
| 11 | pancreatic cancer.   |
| 12 | DR. MIDDENDORF: That was Valerie speaking.                           |
| 13 | DR. WARD: Right. And then it was Tom speaking                        |
| 14 | DR. ALDRICH: Yeah, I said I think that the rationale for including   |
| 15 | the tubular organs in the digestive tract makes a lot more sense     |
| 16 | because it because there's rationale for heavy exposure. If          |
| 17 | there's rationale for environmental causes of pancreatic cancer, I'm |
| 18 | open to it. I don't know that literature. And so I wonder if one of  |
| 19 | the people who's more familiar with that literature would like to    |
| 20 | comment on whether there's evidence of occupational or               |
| 21 | environmental triggers for pancreatic cancer.                        |
| 22 | MS. HUGHES: Catherine Hughes here. I understand that                 |
| 23 | pancreatic cancer's on the fast track to be included under Agent     |
| 24 | Orange for the Veterans Association, the VA.                         |
| 25 | (interference)   |
| 26 | DR. WARD: We're getting some interference from somebody, so if       |
| 27 | everybody would be sure they're on mute when they're not             |
| 28 | speaking.  |
| 29 | MS. FLYNN: This is Kimberly Flynn. As I understand it, there are     |
| 30 | there is an increase in risk for pancreatic cancer from occupational |
| 31 | exposure to diesel and other fossil fuel combustion products.        |
| 32 | Anybody know anything about that?                                    |
| 33 | DR. TALASKA: Glenn Talaska. I couldn't see anything like that from   |
| 34 | any of the PAH studies so that when I looked through the PAHs.       |
| 35 | DR. WARD: There are two diesel studies that just came out and I'm    |

trying to locate them, but it's -- I think -- you know, the evidence we were using was the evidence that was available from the IARC monograph, and diesel is scheduled for re-review, but it was -- their review was not available right now.

**DR. WEAVER:** This is Virginia Weaver. Could I just ask a question of clarification?

DR. WARD: Sure.

**DR. WEAVER:** For the new cancers that we haven't discussed and we haven't included in the document with a rationale for inclusion, I guess that in the document to date we really approached it with a eye to documenting exactly why we were including various cancers and, since we have to finish this document in a timely fashion, it would be difficult to take the additional three cancers and be able to give them the same attention that the cancers that are in the document to date have had. So could we revisit the parking lot issue in terms of what our opportunities would be going forward if we were not to include these cancers today?

DR. WARD: Well, as I understand it, it's quite likely that we may be asked to address petitions -- in other words, if there are future petitions to add other cancers to the list, Dr. Howard has the option of asking our advice on those petitions. And at that point -- you know, if he does ask for our advice, that we would have the opportunity to review the new evidence and consider whether to add those cancers. But it's also my understanding that there's -- I mean it -- we basically do have to reach agreement today, and if -- let's say the sense of us on the Committee -- if the majority of the people felt that one of these three or two of these three cancers should be included, then I think we would just have to write the draft to indicate that, you know, this is the recommendation, this is what the Committee was basing the recommendation on, and you know, the time frame did not permit as full a rationale as what the -- you know, as was provided by the other sites.

**MS. HUGHES:** Catherine Hughes here. On the breast cancer there's recently an article in 2010 by Dr. Liu that PCBs enhance metastic (sic) properties of breast cancer cells by activating the

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ROCK, R-O-C-K, the Rho-associated kinase. It says the conclusions of the summary article I have, it's PCBs enhanced the metastic (sic) propensity of breast cancer cells by activating the ROCK signaling, which is dependent on the R-O-S induced by the PCBs. So that would be possibly one article to consider under breast.

DR. HARRISON: Liz, this is Bob Harrison.

**DR. WARD:** Yes.

**DR. HARRISON:** I don't believe that we have, or at least I have, sufficient information on -- to vote to add additional cancers beyond those that are listed in the current proposal under option two without considering more scientific and epidemiological and toxicological data. And in the preface to the -- to our current draft we're using three criteria. We're using the IARC monographs for limited or sufficient evidence, respiratory and digestive tract cancers where inflammatory conditions have been documented, and then answers for which epi studies have found evidence of increased risk in World Trade Center responder and survivor populations as referenced in Table 4. And if we were going to add other cancers outside of those three criterias (sic) -- which I'm, you know, perfectly comfortable doing -- then we would, I think, need to more carefully review the scientific evidence presented for full consideration by the Committee, and then a vote. But I don't believe that I could vote without having done that first. So process-wise, I guess I'm suggesting that if this Committee needs to reconvene at a future date to review that evidence, then I would, you know, certainly be -- I think that would be the route to go.

**DR. WARD:** Yeah, and as I understand it -- Paul can comment as well -- basically we don't really have the option of saying we need to reconvene at a later date. I think we need to, you know, have both people -- have -- if anyone is making a motion to add any of these three cancers, we need to hear the rationale for that addition, and then we need to have discussion as -- you know, by the Committee, and then we need to take a vote. And as to whether in the future we'll look at those cancer sites again, that's

1 really up to Dr. Howard. 2 **UNIDENTIFIED:** One point of clarification also is I just want to — 3 **DR. MIDDENDORF:** Who's speaking? 4 **UNIDENTIFIED:** -- is on the future list under VA to be added under 5 Agent Orange as well. **DR. MIDDENDORF:** Was that Catherine Hughes? 6 7 **MS. HUGHES:** Yes, it was. 8 **DR. MIDDENDORF:** Thank you. 9 MS. DABAS: Hi, this is Valerie. I have a question. On page 41, the 10 Table 2, select agent that IARC has classified as carcinogenic to 11 humans and related cancer sites with sufficient or limited evidence, 12 2378 tetrochlorobenzoparadoxin (ph), says all cancers combined. 13 And I'm wondering why we haven't used that as our -- as the 14 rationale to at least get pancreas, breast and brain in. 15 DR. WARD: Well, it was -- that was -- that evidence was discussed under the -- under option one. It was specifically cited under 16 17 option one. I don't -- I don't see it as a direct rationale for getting 18 pancreas, brain and breast in. 19 MS. DABAS: Right, but if we're saying that we would include using 20 the rationale that we'd use for digestive system, for identifying the 21 digestive system, adding that particular carcinogen agent to that 22 case, to say that we believe that because the digestive system has 23 been identified as one of the systems that we think has been 24 compromised, to include the other organs, that we also believe 25 that that plus this would get us there. 26 DR. WARD: I'm not sure I follow the logic. I mean I think -- you 27 know, we already discussed including pancreatic as part of the 28 digestive system and the rationale for why -- didn't think it should 29 be included because it wasn't an organ that had direct contact with 30 substances that were passing through the digestive tract or the 31 upper respiratory tract. 32 So Paul, can you help me remember exactly where we are in terms 33 of motions? We did have a motion and a second with regard to --34 **DR. MIDDENDORF:** We have a motion on the table -- up on the 35 screen. The motion is that the Committee recommends adding

1 pancreatic cancer to the list of digestive tract cancers. 2 **DR. WARD:** Okay. 3 **DR. MIDDENDORF:** Below that I just put the digestive tract cancers 4 that were in the motion which passed. 5 **DR. WARD:** So maybe, Valerie -- I think maybe we can't really -- we should probably stick to discussing the pancreatic cancer right now, 6 7 and then address the other cancers separately when there's a 8 motion to do so. So is there any further discussion on the 9 pancreatic cancer? 10 (No response) 11 **DR. WARD:** I would think it's time for a vote on the pancreatic 12 cancer. 13 **DR. MIDDENDORF:** So motion four, which was put forward by 14 Catherine Hughes and was -- if I remember correctly, an 15 amendment by whom? 16 **UNIDENTIFIED:** Valerie. 17 **DR. MIDDENDORF:** Or was it just seconded? 18 DR. WARD: Seconded, I think. 19 **DR. MIDDENDORF:** Seconded by Valerie, is that correct? 20 MS. DABAS: Yes. 21 **DR. MIDDENDORF:** Okay. So the motion on the table is 22 'Committee recommends adding pancreatic cancer to the list of 23 digestive tract cancers.' 24 And going to the vote, we'll do it again alphabetically. Tom 25 Aldrich? 26 DR. ALDRICH: No. 27 **DR. MIDDENDORF:** Steve Cassidy? 28 MR. CASSIDY: Yes. 29 **DR. MIDDENDORF:** Valerie Dabas? 30 MS. DABAS: Yes. 31 DR. MIDDENDORF: John Dement? 32 DR. DEMENT: No. DR. MIDDENDORF: Kimberly Flynn? 33 34 MS. FLYNN: Yes. 35 DR. MIDDENDORF: Bob Harrison?

| 1  | DR. HARRISON: No.  |
|----|--|
| 2  | DR. MIDDENDORF: Catherine Hughes?                                    |
| 3  | MS. HUGHES: Yes.   |
| 4  | DR. MIDDENDORF: Steve Markowitz is not here. Guille?                 |
| 5  | MS. MEJIA: Yes.  |
| 6  | DR. MIDDENDORF: Carol North is not here. Julia Quint?                |
| 7  | DR. QUINT: No.   |
| 8  | DR. MIDDENDORF: Bill Rom?  |
| 9  | DR. ROM: No.   |
| 10 | DR. MIDDENDORF: Susan Sidel?   |
| 11 | MS. SIDEL: Yes.  |
| 12 | DR. MIDDENDORF: Glenn Talaska?                                       |
| 13 | DR. TALASKA: No.   |
| 14 | DR. MIDDENDORF: Leo Trasande?  |
| 15 | DR. TRASANDE: No.  |
| 16 | DR. MIDDENDORF: Liz Ward? No, excuse me, Virginia Weaver?            |
| 17 | DR. WEAVER: No.  |
| 18 | DR. MIDDENDORF: Liz Ward?  |
| 19 | DR. WARD: No.  |
| 20 | <b>DR. MIDDENDORF:</b> Okay, the count I get is nine no and six yes. |
| 21 | The motion does not carry.   |
| 22 | DR. WARD: Okay, so the floor is open for additional motions. Or      |
| 23 | topics for discussion, if not motions.                               |
| 24 | MS. SIDEL: I'd like to make a motion to add brain cancer. I'm        |
| 25 | sorry, Susan Sidel.  |
| 26 | DR. WARD: Is there a second?   |
| 27 | MS. HUGHES: Catherine Hughes, yes.                                   |
| 28 | DR. WARD: Okay. So can we have some discussion on the                |
| 29 | rationale for adding brain cancer?                                   |
| 30 | UNIDENTIFIED: Isn't the brain the largest part of the nervous        |
| 31 | system, and the nervous system interfaces with the circulatory       |
| 32 | system and the lymphatic system, and the pulmonary as well.          |
| 33 | DR. MIDDENDORF: I just want to make sure who excuse me for           |
| 34 | just a second, I who made the motion? Was that Susan Sidel?          |
| 35 | MS. SIDEL: Yes, and Catherine seconded.                              |

1 DR. MIDDENDORF: Catherine seconded, thank you. And is this the 2 correct motion, 'The Committee recommends adding brain cancer 3 to the list of covered conditions'? 4 MS. SIDEL: Correct. 5 **DR. MIDDENDORF:** Okay. MS. SIDEL: Thank you. 6 7 **DR. WARD:** Is there anyone else who wants to speak to the point 8 of the rationale for adding brain cancer? 9 DR. HARRISON: This is Bob Harrison. I would just like to point out 10 I believe that there's some evidence that exposure to solvents, in 11 some studies, increases the risk of brain cancers. I don't know 12 whether solvents, or solvent exposure, was among the World Trade 13 Center. I know that we have identified benzene. 14 **UNIDENTIFIED:** Yeah, I just understand that some of the main floor 15 of the World Trade Centers that was full of solvents -- oh, in the 16 sub-basement, yeah. 17 MS. SIDEL: Even in another -- I'm sorry, Susan Sidel. May I speak? 18 DR. WARD: Yes. 19 MS. SIDEL: Catherine, maybe you can help me out with this, but 20 didn't we talk about there were several doctors' offices in the 21 towers that had X-ray machines? So that would be radiation. 22 MS. HUGHES: Okay, what I understand is there's a large cooling 23 system which had a lot of the solvents in it, it was in the basement 24 and the seventh and eighth floor. 25 **UNIDENTIFIED:** That was (indiscernible). 26 DR. WEAVER: Virginia Weaver. So it would be great to be able to 27 flesh some of this out in more detail. There's data suggesting that 28 formaldehyde increases brain cancer, although apparently it's 29 somewhat population-dependent. We do know that formaldehyde 30 is present in combustion products. There is an increased risk of 31 brain cancer in firefighters, again suggesting that it may be 32 reflecting combustion exposures. However, it's kind of hard to do 33 this on the fly without being able to think through the lines of 34 evidence and the fact that brain cancer did not fall out using our a 35 priori criteria.

1 **DR. DEMENT:** This is John Dement. May I speak? 2 **DR. WARD:** Yes, John. 3 **DR. DEMENT:** I think this is one that's actually harder to come to 4 consensus about than the pancreatic cancer because I think, as 5 Virginia's pointed out, there are some exposures and actually a number of case control studies, too, that point to firefighting and 6 7 solvents as brain cancer risks. But unfortunately, I don't think it -- I 8 don't think the level of evidence has risen to a level that would be 9 sufficient for IARC to classify it as such. There probably hasn't 10 been a review done in a while either, but nonetheless, that sort of 11 dates those data. 12 Also didn't vinyl chloride have some question about brain cancer, a 13 relationship, at one time as well? 14 **DR. WEAVER:** Virginia -- yes, I think it did. 15 MS. HUGHES: And also there was lots of plastics. Think of all the 16 computer terminals that were -- you know, imbedded in plastic 17 boxes, PVC --18 **UNIDENTIFIED:** Carpet. 19 MS. HUGHES: -- and everything like that, carpeting. 20 **DR. WARD:** And so the one thing I can speak to is that in the most recent IARC review brain cancer was not identified as one of the 21 22 sites. I think there were some early findings, but then the later, 23 larger studies did not see excess risk for brain cancer. 24 MS. DABAS: Hi, this is Valerie. I just wanted to know -- Dr. Rom 25 spoke earlier saying that he was doing some work on brain -- if he 26 had any thoughts on this. I might regret it, but... 27 DR. ROM: This is Bill Rom. Beyond what Bob Harrison said with 28 the solvent exposure, I really have nothing to add. And I think this 29 is a type of cancer that's under investigation, but there's no real 30 hard evidence for occupational/environmental exposures yet. 31 **DR. WARD:** I think unfortunately there's been a lot of studies that, 32 you know, were motivated by brain cancer clusters in various 33 industries. And frequently it turns out that there really isn't either 34 an excess risk or there isn't anything in particular that the brain 35 cancers are associated with. So it's been one of the very difficult

1 cancers in occupational health because it's -- you know, there's 2 been actually a lot of studies and they haven't really led to any 3 clear conclusions about the causes -- whether there's an excess and 4 what the causes might be. 5 So I -- I mean if no one has any further comment, we can just call 6 this motion to a vote. 7 **UNIDENTIFIED:** I just have a quick question here. 8 **DR. MIDDENDORF:** Who is that? 9 MS. HUGHES: This is Hughes -- Catherine Hughes. I understand 10 someone has -- if we vote to exclude a particular site, if -- a 11 lymphoma is still -- is lymphoma still covered in a non-covered site? 12 For example, someone has a lymphoma cancer in the brain? 13 **DR. WARD:** To the best of my knowledge, yes. I mean lymphomas are classified as a group, regardless of what site they arise in, so --14 15 and I will -- I didn't include the appendix of sites and histologies, 16 but I will. And I assume that the program -- you know, if the 17 program chooses to accept our recommendations, obviously they 18 will look in detail and make sure that all the relevant sites and 19 codes are included, but I made my best attempt using the SEER 20 database to specify that, and I think basically when -- you know, for 21 certain cancers like lymphomas, regardless of what site in the body 22 they arise in, they're classified as a lymphoma because most 23 cancers do arise in lymphatic tissue all over the body. 24 So Paul, shall we go ahead and have a vote? 25 DR. MIDDENDORF: Okay. So the motion on the table is 'The 26 Committee recommends adding brain cancer to the list of covered 27 conditions.' 28 With the vote here -- Tom Aldrich? 29 DR. ALDRICH: No. 30 **DR. MIDDENDORF:** Steve Cassidy? 31 MR. CASSIDY: Yes. 32 **DR. MIDDENDORF:** Valerie Dabas? 33 MS. DABAS: Yes. 34 DR. MIDDENDORF: John Dement? 35 DR. DEMENT: No.

| 1  | DD MIDDENDODE Windows 51 and                                      |
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| 1  | DR. MIDDENDORF: Kimberly Flynn?                                   |
| 2  | MS. FLYNN: Yes.   |
| 3  | DR. MIDDENDORF: Bob Harrison?                                     |
| 4  | DR. HARRISON: Yes.  |
| 5  | DR. MIDDENDORF: Catherine Hughes?                                 |
| 6  | MS. HUGHES: Yes.  |
| 7  | DR. MIDDENDORF: Steve Markowitz is not here. Guille?              |
| 8  | MS. MEJIA: Yes.   |
| 9  | DR. MIDDENDORF: Carol North is not here. Julia Quint?             |
| 10 | DR. QUINT: No.  |
| 11 | DR. MIDDENDORF: Bill Rom?   |
| 12 | DR. ROM: No.  |
| 13 | DR. MIDDENDORF: Susan Sidel?                                      |
| 14 | MS. SIDEL: Yes.   |
| 15 | DR. MIDDENDORF: Glenn Talaska?                                    |
| 16 | DR. TALASKA: No.  |
| 17 | DR. MIDDENDORF: Leo Trasande?                                     |
| 18 | DR. TRASANDE: No.   |
| 19 | DR. MIDDENDORF: Virginia Weaver?                                  |
| 20 | DR. WEAVER: No.   |
| 21 | DR. MIDDENDORF: And Liz Ward?                                     |
| 22 | DR. WARD: No.   |
| 23 | <b>DR. MIDDENDORF:</b> Eight nos, seven yes. Eight no, seven yes. |
| 24 | DR. WARD: Thank you, Paul. So additional motions?                 |
| 25 | MS. FLYNN: The Committee recommends this is Kimberly. The         |
| 26 | Committee recommends the addition of breast cancer to the list of |
| 27 | covered conditions.   |
| 28 | MS. SIDEL: I second it. I'm Susan Sidel. I second her mo          |
| 29 | Kimberly's motion.  |
| 30 | DR. WARD: Thank you. So shall we have a dis have people who       |
| 31 | want to speak to the rationale for adding breast cancer?          |
| 32 | DR. MIDDENDORF: Just one quick thing, was that Kimberly who       |
| 33 | made the motion?  |
| 34 | MS. FLYNN: Yes, it was.   |
| 35 |   |
| 33 | DR. MIDDENDORF: Okay. And Susan seconded?                         |

1 MS. SIDEL: I did -- seconded it. 2 **DR. MIDDENDORF:** Okay. And is this the correct motion, 'The 3 Committee recommends adding breast cancer to the list of covered 4 conditions'? 5 MS. FLYNN: Yes. 6 **DR. WARD:** So I know people have -- several people have spoken 7 on the rationale for breast cancer before, but it probably would be 8 useful at this point, even if -- if you've said something before, say it 9 again, because we really need to lay out the rationale as strongly 10 and clearly as possible so that the Committee can consider whether 11 they think that there's sufficient rationale for adding it. 12 MS. HUGHES: Hughes, one, there were many -- there was 13 endocrine disrupters there; two, stress can attribute to increased 14 cancer; three, Agent Orange -- breast cancer's on the fast track for 15 that. 16 **DR. WARD:** Anyone else? 17 MS. HUGHES: I'm sorry, and four, there have been limited studies 18 of women in occupational health. 19 MS. DABAS: Hi, this is Valerie. I think one of the things that I read 20 in Environmental Health Perspective was the estrogen effect and 21 BPAs, and that exposure to BPAs can cause the body to produce 22 estrogen and then lead to breast cancer. So I think when we 23 looked at plastics that were at the World Trade Center, some of the 24 things that they talked about were cleaning products, plastic from 25 computers, linoleum from the floors, the vinyls, synthetic 26 fragrances and fabrics such as carpet that were burning. So I think 27 there is some indication that, you know -- that this could have 28 caused increased estrogen in women that's causing the breast 29 cancer. 30 **DR. WARD:** So does anyone who's not in favor of adding breast 31 cancer want to speak to their rationale? 32 **DR. QUINT:** Well, before you do that -- this is Julia. 33 **DR. WARD:** Okay. 34 **DR. QUINT:** I haven't decided one way or the other yet, but I just 35 want to say that there are lots -- there are data, studies, both in

vivo and epidem-- animal studies and human studies, epidemiological studies indicating an association between PCBs and breast cancer. And also there is a new -- and they're not consistent, I should say that, so that gives me some pause. But there is a new -- fairly new study showing increase in breast cancer metastasis with PCBs and a specific mechanism that's been proposed, and that was shown both in vivo and in cell cultures. So I think we have a specific WTC exposure of PCBs linked to breast cancer and, as I said, the data are not consistent in terms of the association. But the new study showing an increase in breast cancer metastasis, that is just one study, but it's pretty solid, seemingly, evidence. I think it adds some weight.

**DR. WARD:** Glenn, you were -- I think you were the person who did most of the work on exposure levels to PCBs. Do you want to comment?

**DR. TALASKA:** Well, you know, the data -- there weren't data that indicated that those -- at least biological. But again, subject to the limitations of all the data that were collected, a relatively small number of people that were collected after the fact, but fairly persistent compounds, PCBs and -- so they should have been increased in the people that were measured by the CDC. And I'm just checking the wording that we did -- no, and I don't believe that they were.

The dioxin is a similar thing. We had the window films that showed that there were relatively high levels on the -- in the windows, but there weren't elevated levels of any of the dioxins in the people that were studied by -- again, by the CDC.

Then there were increases -- let's see, on one congener was increased in exposed firefighters. Only one of the congeners in the mean values were 27.8 parts per trillion for all site firefighters; 30 parts per trillion for those present at the collapse; 26.2 for those arriving day one or day two, and 30.6 for those in special operations. The firefighters not at the site had a lower average for that one congener, so that was elevated. In retrospect, the average was -- for the Agent Orange, the average, measured ten

years after their exposure, was -- in the ranch hand study was 49 parts per trillion and ranged to 313. So you know, they had -- they had ten years for the stuff to go away. It has about a seven-year half-life, if I remember correctly, and they were -- and their levels were several times higher than what were seen in any of the people that were measured in the early -- as far as we know, since we didn't get the range -- in the -- at the World Trade Center. And that was only one congener, and it wasn't for TCDD itself, which -- that's the biggest one in terms of exposure for dioxin and/or for PCBs.

I'm re-looking at what we wrote. They certainly were at the site,

I'm re-looking at what we wrote. They certainly were at the site, but the lev-- the air levels were said to reduce -- be reduced fairly quickly. And again that's to be expected because PCBs are -- have a really low vapor pressure. But you know, there still could be dermal absorption from them, so that's the other side of the coin. Again, Edelman did not see a difference between any of the mean values of the firefighters or people -- or the firefighters who never entered the Ground Zero site.

Dahlgren did see levels in -- I think he studied seven first responders and that three were above the 75th percentile, two above the 90th and one above the 95th percentile, which would probably be unusual. But again, they -- that report was limited because they didn't say how these people -- the seven people were selected, although they did see some elevation in PCBs, too. So the data are mixed -- there is no other way to put it -- in terms of the exposure for PCBs and dioxin. It seems like there was an enormous amount of dioxin in the air to begin with, but at least it seems from the data that either it didn't get into people readily, which is a very good thing -- and with the PCBs there's some indication of exposure to some people to elevated levels of PCBs, but those data are limited.

**DR. WARD:** Good. And this is Liz. I think, you know, from my point of view, you know, one of the things that we didn't look at and we -- there probably isn't enough data to look at, but probably should be on the agenda for future research, is kind of the effects

of the stress related to the World Trade Center exposures and how that might have affected the endocrine system, and that might have some direct bearing on breast cancer. But at this point, the studies just aren't -- I mean the studies haven't been done to show that.

I guess the other exposure that has been related to breast cancer is

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shift work. But again, you know, IARC did an evaluation of that and I think it -- based on limited evidence in humans, but then subsequent studies have not been confirmed at the early association. So -- and I do agree with the comments and I just don't know how to deal with it that, you know, there have been very few -- because so few women were involved in the industrial occupations that form a large part of the base of our knowledge about occupational carcinogens, we really don't have good information about the effect of many carcinogens on causing cancer of the female breast. Even the male breast is such a rare cancer that it wouldn't be picked up in occupational studies. MS. FLYNN: This is Kimberly, excuse me, but I think this is actually a perfect instance where we really do need to lean on the precautionary principle. We are not going to have this information, number one. Number two, we are not just talking about shift work. We're talking about shift work on steroids. I mean we're talking about extreme shift work that was being done by female responders who were simultaneously being exposed to, you know, plastics fumes, who were simultaneously being exposed to 2378 PCBD, who were simultaneously being exposed to probably a range of xenoestrogens in World Trade Center dust and smoke. I guess I'm asking whether or not there's some possibility of pulling together a rationale here when we have a population that is -- you know, whose health impacts are simply not ever going to be addressed by occupational studies, you know, in the next 15 to 20 years. And I guess I want to throw in that Edelman -- you know, I don't want to repeat my comments, but Edelman is extremely limited. And Glenn, you actually raised at least three important criticisms with respect to the inadequacy of the Edelman -- of the

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information provided in Edelman. I'd also like to say that we're talking about, you know, exposures that are bio-- are cumulative and we're talking about one stint on the Pile, one stint in downtown where, you know, had Edelman come back and retested, he might have gotten much higher blood lipid levels.

DR. TALASKA: This is Glenn. My major concern with Edelman, at least to the PAHs, was the fact that those things have a fairly short half-life, and yet he didn't sample until 21 days after the peak. With dioxin compounds, as I was trying to point out in the -- by bringing up the ranch hand study, you know, when they sampled those people ten years after their exposure, they were still halfagain higher than the highest ones that were reported at the -- at Ground Zero. And so that was a ten-year lag, where it would have shown up relatively quickly after the exposure and it should have been maintained for 21 days if you can see it ten years later. That's my concern with, you know, making the inclusion. You know, philosophically and personally, it's something that -yeah, you'd like to see everyone -- this particular disease covered because there's a possibility that perhaps there was some exposures in some individuals, and that a few individuals whose disease may be related to those exposures. You know, there's a possibility that that would be happening, based upon the data, because we don't have the ranges. We don't know what -- what -the peak that Edelman saw for most of the markers that he measured. But it's -- it would -- at least from -- the types of exposures relative to what was seen in other places, it seems like that would -- seem to me the probability would be that there would be very few of those.

So on -- you know, at one hand I would support the notion, but the science just isn't there to say that this is a condition where everybody would -- or you would expect that people would have this in an elevated probability. But I'm sure on an individual basis there probably is somebody -- I can't say I'm sure. There may be on an individual basis somebody who had a high level that just wasn't documented because they weren't with some of those --

directly with some of the transformers or in the smoke from a particular transformer fire that had some in it. You know, that's where the chance is, as far as I can see.

Does that make sense?

DR. WARD: That makes sense to me -- this is Liz. But even so,

**DR. WARD:** That makes sense to me -- this is Liz. But even so, though, there's not a strong established association between PCBs and breast cancer.

DR. TALASKA: Correct.

**DR. WARD:** So it's not -- I mean so it's not like we're saying there is a strong epidemiologic association and if someone happened to be in the plume when -- you know, near a transformer fire, then that would have been a reasonable assumption that they would have gotten a high exposure that would result in breast cancer. So the problem is we don't have strong evidence for an association between PCBs or TCDD and breast cancer, and we don't have evidence -- we don't have much evidence that there was elevated exposure in the population as a whole.

MS. FLYNN: This is Kimberly. I think, again -- I mean, and I won't rehearse this, but the idea that we don't have that kind of exposure data doesn't mean that those exposures didn't happen, number one. And number two, I guess I'm wondering if there isn't any way for us to craft a similar rationale to the rationale for coverage of pediatric cancers, to cover female breast cancer, because we have a small group of women in the monitoring program and we have a very small group of women being seen at the World Trade Center Environmental Health Center. We don't really have the possibility of getting, you know, large enough numbers to be able to see an up-tick.

**MS. SIDEL:** Hi, this is Susan. Could I speak, please?

**DR. WARD:** Sure.

**MS. SIDEL:** You know, I have such a tough time with basing anything on exposure data because it is so faulty, and it's almost as though the people that really needed the exposure data to be accurate are the ones that are sort of being penalized because it isn't, and so that's what sort of makes it really tough for me on a

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moral basis.

The other thing is that women have just not had any kind of special consideration whatsoever in the program -- well, maybe a little bit over at Bellevue, but I know that in the responder programs there's no special studies that deal with women's health and I know that a lot of women have been impacted in very specific ways. It's just a fault of the program because it's -- you know, you're not seeing large numbers of women so there's a bias generally. And it's difficult because, you know, we're recognizing that there's a problem, but we're not in a position to do anything about it because that would be prol-- you know, that's not the policy. So I just sort of feel as though there has to be some other way that we can get this in because I just don't think that you'll ever get the kind of research that you need because no one is going to -- no one is going to really do that research based on the numbers of people that we have in the program, the number of women. It seems -you know, ten years out it doesn't seem like anybody's really interested in studying women's health.

MR. CASSIDY: Steve Cassidy, can I say something?

DR. WARD: Sure, go ahead, Steve.

MR. CASSIDY: I mean I know that the fire department is doing an EMS study. I know there are a lot of women included in it. It's frustrating that the results are not available at this time. It's just frustrating that we don't have more data, but I know there is an extensive study being done of EMS and they have a significant population of women involved, to my knowledge.

**DR. WARD:** Thanks. And I also think it's -- it's not exactly analogous to childhood cancer because the expected incidence of breast cancer in the population is much greater than the expected incidence of childhood cancer. So I think that even if you have relatively small numbers of women in studies, you have more opportunity to actually see an increased risk, if there is one.

**MS. HUGHES:** Catherine here. What if the age onset happens at an earlier age than normal?

DR. WARD: Well, in the write-up of the rare cancer sites we did -- I

mean and this is just a proposal and, you know, it's kind of something that the program would have to work on implementation of, but the con-- at least conceptually the idea was one would look at cancer sites by at least decade of age. So for example, if someone got breast cancer and they were 25 years old, that would likely qualify as a rare cancer. So if -- because it is, you know, reasonable that some cancers -- you know, what you would see is a shift towards earlier age at diagnosis if there was an increased risk.

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**DR. QUINT:** This is Julia. One of the issues, as I understand it, with PCBs -- and this is based on just one study -- is metas-- you know, the metastasis issue, so that not so much causation with PCB but this new -- this study I mentioned, and I can send you the reference -- show that PCBs actually, you know, cause the breast cancer to metastasize to other sites, which would end up, you know, going from treatable possibly to fatal cancer in women if this is really true -- I mean if this bears out down the line. I know the specific mechanism -- you know, reactive oxygen species generated by the PCBs that activated a specific site mechanism that caused it. So I guess my question is whether or not, in making recommendations to the Director, that we should consider, you know, a cancer that -you know, an exposure that could cause a cancer to metastasize, whether or not that would be considered an exacerbation of an existing condition or something like that, it if turns out -- the exposure data side, I know there are issues with that and I'm not sure how many women were actually included in Edelman's study, but -- so the question is whether or not, if it turns out that PCBs could, you know, influence metastasis of breast cancer, whether or not that would qualify in terms of the -- what we're asked to recommend here, you know, 'cause I'm not talking about causation 'cause those data are inconsistent. But if it turns -- I mean would that be a legitimate area to comment on -- to make a recommendation on, or to base a recommendation on? **DR. WARD:** Well, I can -- I think I can give you an off-the-cuff opinion. I mean I think if there was, you know, a body of evidence

that had been -- you know, where there was -- you know, it wasn't 1 2 just this was the first study and it didn't -- that -- if there was a 3 consistent body of evidence that showed an association between 4 PCB levels and likelihood of metastasis, then I don't think -- I don't 5 necessarily know that it would -- how it -- how the final decision would be made at this point in time given the criteria that we --6 7 that started with. I can say, as someone in the cancer field, this is 8 not something that -- you know, the effect of environmental 9 exposures on likelihood of metastasis or likelihood -- you know, or 10 on -- or even on survival after diagnosis is not an area that's been 11 really well-researched, so it's not something where I think one 12 would readily find a body of literature or a lot of precedents about 13 how that type of data was handled in, you know, regulatory or 14 advisory bodies. But -- but certainly -- you know, I think if there 15 was a solid body of evidence showing that a particular exposure that was present at the World Trade Center, you know, was 16 17 associated with an increased likelihood of metastasis, then maybe 18 one could -- one could even think about including, you know, more 19 advanced cases of particular diseases in the category as World 20 Trade Center-related conditions. 21 So are there any further comments before we bring this motion to 22 a vote? 23 **UNIDENTIFIED:** Just wanted to answer the question, I don't believe 24 there were any women studied by Edelman. I could be wrong --25 **UNIDENTIFIED:** Yes. 26 **UNIDENTIFIED:** -- it wasn't indicated. 27 **UNIDENTIFIED:** I think you're right. I'm looking at it right now. 28 UNIDENTIFIED: Yeah, I am, too, and they don't mention anything 29 at all about gender. 30 **UNIDENTIFIED:** Gender, yeah. 31 **UNIDENTIFIED:** So, just to clarify. 32 **DR. WARD:** Okay. So any further comments or questions before 33 we call for a vote? 34 (No response)

DR. WARD: Okay. Paul?

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| 1  | DR. MIDDENDORF: Okay. The motion before the Committee is      |
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| 2  | 'The Committee recommends adding breast cancer to the list of |
| 3  | covered conditions.'  |
| 4  | Okay, Tom Aldrich?  |
| 5  | DR. ALDRICH: Yes.   |
| 6  | DR. MIDDENDORF: Steve Cassidy?                                |
| 7  | MR. CASSIDY: Yes.   |
| 8  | DR. MIDDENDORF: Valerie Dabas?                                |
| 9  | MS. DABAS: Yes.   |
| 10 | DR. MIDDENDORF: John Dement?                                  |
| 11 | DR. DEMENT: No.   |
| 12 | DR. MIDDENDORF: Kimberly Flynn?                               |
| 13 | MS. FLYNN: Yes.   |
| 14 | DR. MIDDENDORF: Bob Harrison?                                 |
| 15 | DR. HARRISON: No.   |
| 16 | DR. MIDDENDORF: Catherine Hughes?                             |
| 17 | MS. HUGHES: Yes.  |
| 18 | DR. MIDDENDORF: Guille?                                       |
| 19 | MS. MEJIA: Yes.   |
| 20 | DR. MIDDENDORF: Julia Quint?                                  |
| 21 | DR. QUINT: Yes.   |
| 22 | DR. MIDDENDORF: Bill Rom?                                     |
| 23 | DR. ROM: No.  |
| 24 | DR. MIDDENDORF: Susan Sidel?                                  |
| 25 | MS. SIDEL: Yes.   |
| 26 | DR. MIDDENDORF: Glenn Talaska?                                |
| 27 | DR. TALASKA: No.  |
| 28 | DR. MIDDENDORF: Leo Trasande?                                 |
| 29 | DR. TRASANDE: Yes.  |
| 30 | DR. MIDDENDORF: Virginia Weaver?                              |
| 31 | DR. WEAVER: No.   |
| 32 | DR. MIDDENDORF: Liz Ward?                                     |
| 33 | DR. WARD: No.   |
| 34 | DR. MIDDENDORF: Okay. Okay, I have nine yes and six no. The   |
| 35 | motion would carry.   |
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1 DR. WARD: Okay, so now what we --2 **DR. MIDDENDORF:** Liz, before moving on, I need to clarify one 3 thing. A question for Bob Harrison, your vote on motion number 4 five, 'The Committee recommends adding brain cancer to the list of 5 covered conditions' -- could you restate your vote? I mean it doesn't make a difference in terms of the outcome, but it does 6 7 make a difference in terms of being sure that we're accurate. 8 **DR. HARRISON:** Yes, that was yes. 9 DR. MIDDENDORF: It was yes. Okay, thank you. Back to you, Liz. 10 DR. WARD: Okay. So as I understand it, what we need to do now 11 is really draft the text providing the rationale for recommending 12 that breast cancer be listed as a World Trade Center-related 13 condition. And maybe some of the Committee members that voted 14 yes could try to give Paul some language that he could incorporate 15 into the document, hopefully modeled along -- you know, I mean similar to the kind of information that we provided for the sites 16 17 that were initially included. 18 (Pause) 19 **DR. WARD:** So I guess one rationale was that several of the -- well, 20 I guess one big part of the rationale is that the li-- you know, that 21 much less is known about occupational/environmental causes of 22 breast cancer than other cancers because very few studies have 23 been done in women. That was one -- in women in industrial 24 occupations. That's one point. I don't know if it would be the first 25 point. 26 Paul, are you trying to get this? 27 DR. MIDDENDORF: Yeah, I'm trying to find out where you are at 28 the moment. 29 **DR. WARD:** Well, we're nowhere because we're adding a new 30 cancer site -- I mean --31 **DR. MIDDENDORF:** So do you want this at the bottom of the list? 32 DR. WARD: Right. 33 **DR. MIDDENDORF:** Okay, for option two. 34 **DR. WARD:** Well, yeah. I mean I guess we want to put it before --

DR. MIDDENDORF: Do you want to draft that now or do you want

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1 to work on the other two possible motions? 2 **DR. WARD:** What other two possible motions? 3 **DR. MIDDENDORF:** One on... DR. WARD: I mean, as I recall, there were -- I mean, at least with 4 5 regard to cancer sites, there were three possible motions, two of which we voted no and one of which we voted yes, which is breast. 6 7 So --8 DR. MIDDENDORF: I guess I was thinking of the rare cancer and 9 childhood cancer. 10 **DR. WARD:** I was assuming that that was included in the --11 **DR. MIDDENDORF:** Included in the larger list? 12 DR. WARD: I thought so. Was everyone else --13 **DR. MIDDENDORF:** Okay, rare cancers is there, childhood cancers 14 is there, yes. They are there. Okay. 15 MS. DABAS: Yes, but -- this is Valerie -- I don't think we -- I think there was some questions about the definition of rare cancers that 16 17 was brought up on email. 18 **DR. WARD:** There were -- well, I don't recall. I mean does anybody 19 have a problem with the way it -- it's not specifically defined here. 20 If you look at -- in the cover letter, and then if you -- I mean in the 21 cover letter it's not -- a specific cutoff isn't given. But if you go 22 back and look at the supporting document -- I'm trying to find it, I 23 think on page 27. So basically what it -- what it's saying on page 27 24 is that it's acknowledging that there's lots of different ways that 25 cancers are classified. Most commonly in epidemiologic studies 26 they're classified by organ site of origin, but they're -- all cancers 27 that are diagnosed are -- have essentially two major classifications. 28 One is with regard to the organ site and the other is with regard to 29 the histology. So for exam-- and the two examples we cited here 30 are -- so for vinyl chloride (indiscernible) exposure, the cancer site 31 that was most strongly associated with it was angiosarcoma of the 32 liver, which is a specific histological site, distinct from the more 33 common type of liver cancers, although ultimately it turned out that vinyl chloride was associated with the common type as well, 34 35 but similarly for bis(chloromethyl) ether, it was really a cluster of

small cell carcinoma or oat cell carcinoma that was associated with that specific chemical. So what we're saying here is that we would really want the classification of rarity to be based either on site or site plus histology to allow for that. We're also saying that we would want the classification of rare cancers to be based -- you know, based for -- based on a patient's age, gender. For example, breast cancer in men would be rare; it wouldn't be rare in most age groups in women. So I think the idea here was to give the program general guidance, but not to specify -- I mean there were some email conversations that, you know, 15 per-- you know, you wouldn't want to classify 25 percent of cancers that happen in the United States as rare. But I think we were trying to give the program some general guidance, and then they would operationalize the guidance. But the idea would be to be really inclusive of various options by which a cancer could be called rare.

**MS. DABAS:** Okay, thank you. Sorry, I didn't see that part -- portion of the -- that included the age. Sorry.

**DR. WARD:** So -- but -- so before we go into the rationale for adding breast, are there any other motions that people want to bring to the floor before we work on the language for the breast rationale, and then we work on -- we ask for any factual errors that were found in the documents, any editorial suggestions? **MS. DABAS:** Hi, it's Valerie again, I'm sorry. I just -- I wanted to get a vote on the prostate cancer and the rationale behind why we chose to exclude the prostate cancer. The three rationales that we

used was IARC was -- which I believe prostate is on there in the second section of that. Also we used epidemiological studies and it appeared in the fire department studies, and we all are aware that it will appear in the other two studies that are coming shortly. And then when it goes to biological plausibility as far as inflammation and so forth, I think that -- you know, it fit two -- at least two of the three criteria that we put -- fit at least in two categories and for others all it needed to do was fit in one, so I think that -- I'd like to see a vote on the prostate cancer as well as some discussion on the rationalization for removing it.

1 **DR. MIDDENDORF:** I think the vote has already taken place. 2 DR. ALDRICH: This is Tom Aldrich. It's not right that the fire 3 department say is positive for prostate. Actually it was -- did not 4 show increased prostate when compared to the high-exposed 5 firefighters. 6 **DR. WARD:** Yeah, and I picked it up initially because I was really 7 using -- I didn't want to -- I wanted to put things on the table and 8 not screen them out so, you know, there was one positive signal for 9 prostate cancer which was the comparison of exposed to the 10 general population, but then when you went deeper the evidence 11 really was not -- evidence was really not in favor of the prostate 12 cancer association. So I think, you know, that the -- that what Paul 13 is saying is that the motion to exclude prostate cancer has already 14 carried and there was discussion around that motion, so that this 15 motion is not really in order at this point in time. MS. DABAS: I'm not sure that's the case. I believe that the motion 16 17 that was put was to include everything else but prostate, but it 18 wasn't to specifically exclude prostate. And I think I would like to 19 see a vote on the record as to the exclusion of prostate as well as 20 some justification on the record for that. 21 **DR. WARD:** Okay, Paul, what is your recommendation? 22 **DR. MIDDENDORF:** Well, we've -- to revisit prostate we'd need a 23 motion to reconsider that vote. 24 MS. DABAS: It's Valerie, and I would like to put a motion to 25 reconsider the prostate -- inclusion of prostate. 26 MS. HUGHES: Second -- Catherine Hughes. 27 **DR. WARD:** So I think, though, what Paul is saying is that -- and I'm 28 not saying we should do this, but I think Paul was saying to 29 reconsider the prostate we would have to reconsider the entire 30 vote on including the entire list and the modification of eye. Is that 31 what you're saying, Paul? 32 **DR. MIDDENDORF:** I think we can just reconsider -- basically I was 33 -- an amendment to that that removed prostate, so I think we can go ahead and -- hold on just a second. 34 35 Motion would be to reconsider the entire previous vote because

1 prostate was specifically excluded. 2 MS. DABAS: Paul, what I'm asking is that we vote to consider 3 prostate; not to reconsider the motion, but to -- to vote for the 4 inclusion of prostate cancer. 5 **MS. HUGHES:** Catherine, second it, just prostate only, though. **DR. WARD:** So Paul, are you comfortable with just taking that vote 6 7 for the record? 8 DR. MIDDENDORF: Yeah, I -- I think we can do that. So let's --9 restate that motion. What is the motion? 10 MS. DABAS: The motion is to approve prostate cancer as part of 11 this recommendation. 12 **DR. MIDDENDORF:** Being the -- 'The Committee recommends 13 adding prostate cancer to the list of covered conditions'? 14 MS. DABAS: Yes. **DR. WARD:** And we have a second? 15 16 MR. CASSIDY: Steve Cassidy, second. 17 **DR. WARD:** So is there any further discussion on the motion? 18 **DR. DEMENT:** Yeah, this is John Dement. Can I speak, please? 19 DR. WARD: Yes. 20 **DR. DEMENT:** You know, I think we do have some inconsistency in 21 the approach with regard to prostate cancer, and I think the prior 22 vote tied it in with the all -- approving the entire list, and also we 23 had the eye cancers in there. And I personally was torn with that 24 decision, and I think if we apply our rationale -- and the rationale 25 has to do with exposures to arsenic and cadmium, among other 26 things -- then I think prostate is legitimately one that ought to be 27 considered. 28 **DR. WARD:** Okay. Anyone else who would like to have discussion 29 before we vote? 30 DR. WEAVER: Virginia Weaver, and I have some concerns about 31 prostate because we could do more harm than good. In this 32 current environment where there's so much concern about the 33 appropriate technique to screen for prostate, and we know that we 34 pick up cancers that may never actually become metastatic and 35 cause significant disease but the surgery can be quite disabling, I

have concerns about including a cancer when there's less certain evidence and concerns about the screening approach.

DR. TALASKA: Glenn Talaska, I have to chime in here, too. I think my reservations with prostate cancer have to do with the one carcinogen that we -- that is known to be a prostatic carcinogen and that's cadmium. And again, going back to the Edelman data with all their flaws, the levels of cadmium -- which has a very long half-life -- in the firefighters at the site was lower than the firefighters who never entered the site, and they were both relatively low levels of cadmium. So that exposure -- you know, they weren't anywhere near elevated, compared even to population levels. And they were lower in the firefighters who entered the World Trade Center than those who were -- who never entered it and were used as the control group for that study. So it would take away that one exposure that we have any exposure data on.

**DR. WARD:** This is Liz -- no, go ahead.

**MS. FLYNN:** I'm sorry, this is Kimberly. I do want to point out, however, that arsenic is also linked with prostate cancer and that, again, the absence of data does not indicate the absence of exposure. So Edelman didn't capture arsenic.

And the second thing I want to say is, while I understand Virginia's hesitations, I think that those fall outside of the purview of the STAC. I think those issues of screening and whether or not, you know, there would be too many surgeries, all come under the purview of implementation of those implementing STAC recommendations.

MR. CASSIDY: Steve Cassidy.

**DR. WARD:** Go ahead.

MR. CASSIDY: I agree with that last comment about being concerned about surgeries. I mean I don't think that has anything to do with our decision. It may be a legitimate concern, but has nothing to do, in my view, with whether or not we consider prostate cancer being included.

And the other comment is that I'm certain not being at the World

Trade Center was better than being at the World Trade Center, whatever those reports indicate about cadmium. That doesn't make any sense whatsoever.

**DR. WARD:** Yeah, this is Liz, and I guess, you know, the things that are weighing on my vote is the fact that the -- you know, the epidemiological data for cadmium and arsenic in prostate is relatively weak, and essentially the study of firefighters was essentially a negative study, not showing an association with prostate cancer and the fact that we really have very little previous evidence of prostate cancer being associated with occupational/environmental exposure, so I guess -- you know, in my mind the -- that the ration-- you know, the rationale for expecting that there will be an association is relatively weak compared to many of the others. And -- yeah, that's basically where I'm coming from.

**MS. SIDEL:** Hi, it's Susan Sidel. May I ask a question?

**DR. WARD:** Sure.

MS. SIDEL: What is the average age for prostate cancer, because for some reason in my mind I thought it was like older men and we were seeing it in younger men, that that was one issue. And that the other issue was that -- I remember someone coming in to testify about how seclusive (sic) it was in her father's case and that usually it's -- it doesn't -- it's not quite as rapid of a progression as what happened with her dad. And I was wondering if that -- you know, if there's somehow we can carve out like exceptions to general rules, or is that getting into policy?

**DR. WARD:** Well, that's why -- you know, that's why we talked about age in the rare cancer thing, so -- so if some -- you know, rates of prostate cancers start going up once you hit about age 45, you start getting an increase in incidence of prostate cancer. So our recommendation was that the program really take age into account, and so if someone is diagnosed with prostate cancer at age 30, then they're -- you know, you would look at the expected incidence of prostate cancer at let's say age 20 to 30 or 30 to 40 as your definition of a rare cancer. So that was specifically -- I mean

so that -- so someone diagnosed with prostate cancer at a really early age would be picked up by the rare cancer.

MS. SIDEL: Right.

**DR. WARD:** But the other thing is, you know, comparing the average age at which cancer is diagnosed is a really tricky business. So for example in the firefighters' study they excluded everyone over age 60 from the study, and the vast majority of people in the population were much younger than 60, so it almost -- it almost has to be true that the average age of diagnosis of prostate cancer would be much lower than in the general population 'cause you didn't have anybody over the age of 60 in that study.

MS. SIDEL: Yeah, so it gets skewed, yeah.

**DR. QUINT:** This is Julia. In addition to the LeMasters' meta-analysis of firefighters and showing -- I think it was, you know, 1.28 increase of prostate cancer, the IARC also did a meta-analysis after the LeMasters study which included two new epidemiological studies and also found, again, an increase in prostate cancer. That's in Volume 98 of the monograph.

So it seems that, you know, you keep finding prostate cancers among workers -- firefighters in this case -- who have, you know, the exposure to some of the same things that were -- just but more so at the World Trade Center. So I know this has been used to sort of indicate that firefighters have, you know, a propensity for prostate cancer, and it wasn't increased based on the World Trade Center exposures, and I would say that possibly we didn't see any increase because, you know, these -- they're having these exposures all the time and it's increased their -- the rate of prostate cancer. So I'm going on the basis of like -- typical -- you know, all of these mixtures of exposures literally being related to an increase in prostate cancer based on lots of studies now, two meta-analyses and lots of epidemiological studies and you -- it just won't go away. So it seems to me there is something there.

**MS. HUGHES:** Catherine Hughes here. Is brain cancer considered a rare cancer?

DR. WARD: Well, I mean the -- well, the -- you know -- well, it's a

lot rarer than lung and prostate and colorectal and breast. Again, where you draw the line -- you know, I'm not sure where it will fall when you draw the line, but it -- like I say, it is a fairly uncommon cancer compared -- in most age groups compared to many of the others we're talking about.

**MS. MEJIA:** This is Guille. I really do have a concern about voting for prostate cancer when in a prior motion we had already voted to exclude it, so I just wanted to chime in.

But the other thing is that we have to also consider a lot of surveillance that has taken place with prostate cancer and all the initiatives that have been undertaken by many public health departments and organizations to increase awareness of prostate among the male population, so -- you know, so there's -- there's going to be a lot more people -- a lot more men identify with prostate as a result of some of these screenings.

**DR. WEAVER:** This is Virginia, and I think that's a very good point. Bob Harrison had made that, that surveillance bias for prostate cancer is probably a big contributing factor to the increased rates that are observed in men. And once again it just makes me anxious, if we're not sure exactly how we should be screening and when we should be doing surgery, that we could do more harm than good.

**DR. WARD:** Yeah, I think that the surveillance bias makes it really very hard to interpret epidemiologic studies for prostate. It -- because even if you look at the long-term incidence rates for prostate over time in the U.S., there's this huge peak in incidence when the PSA screening was introduced. And what's even stranger, there's also a little peak in mortality, and I -- we think it's just -- that peak in mortality is not really due to more men dying of prostate cancer, it's just that when physicians were filling out the death certificates, you know, their awareness of prostate cancer and -- was increased and they -- and more cases were getting diagnosed so they were being included on the death certificate, but they weren't really -- it wasn't that more men were dying of prostate cancer. So when you have one of these cancers that is so

1 influenced by -- you know, there's such a large reservoir of 2 prostate cancers in men that are not systematic and would not be 3 diagnosed, except for the PSA test, that it just makes it incredibly 4 hard to do, you know, good epidemiologic studies. 5 MS. DABAS: Hi, this is Valerie. I mean I think that we -- my understanding is FDNY takes the PSA test, regardless, anyway. So if 6 7 you're looking at the World Trade Center group, this was 8 something that they were doing ordinarily prior to, so I'm not sure 9 how surveillance bias falls into a group that was already getting 10 monitored, especially when they're looking at another group in a 11 similar circumstance. 12 DR. WEAVER: This is Virginia. And that's why there's an increased 13 rate in both the exposed and unexposed firefighters 'cause both of 14 them have been screened for prostate cancer. 15 MS. DABAS: But I assume that there's a difference in the rate between the exposed and the non-exposed, and that's what we're 16 17 looking at. 18 **DR. WEAVER:** The rates are pretty similar. They're both elevated. 19 MS. DABAS: But to a different degree. 20 **DR. WARD:** No. Well, does anybody have the study in front --21 **DR. ALDRICH:** (Unintelligible), I mean the rates are statistically 22 identical. The SIR ratio, which is the ratio of the SIR for the 23 exposed to the SIR for the unexposed, was 1.11 with a confidence 24 interval in the range of some .77 to 1.59. You can't get closer to 25 one than that. There's no dif-- there's no statistical difference, 26 there's no meaningful difference, in those rates. 27 **DR. MIDDENDORF:** And that's Tom Aldrich speaking. 28 **DR. ALDRICH:** I'm sorry, I should have identified myself. 29 MR. CASSIDY: Does anybody have any information on studies that 30 would outline how long after an exposure that people would 31 expect to get prostate cancer? 32 **DR. MIDDENDORF:** And that's Steve Cassidy. 33 MR. CASSIDY: That's Steve Cassidy, yes. 34 **DR. ROM:** This is Bill Rom, and I'm just signing off and turning my 35 vote over to Tom Aldrich 'cause I have a grand rounds speaker to

1 introduce, but I think that prostate is the problem of over-2 diagnosis, with no occupational association. 3 **DR. MIDDENDORF:** Unfortunately, Bill, if you leave you cannot 4 have someone vote as a proxy for you. 5 **DR. WARD:** That does bring up the issue. It is now five minutes to 5:00 and, you know, we are in danger about those people who have 6 7 other commitments have to leave. So I -- with regard to Steve's 8 question, though, I think -- I mean I haven't done a literature 9 search on that specific point, but there are so few studies 10 documenting what the causes -- you know, documenting clear 11 causal factors for prostate cancer that it would -- you know, I don't 12 think you'd find studies that were able to define what the length of 13 time was between the exposure and the outcome. 'Cause for that, 14 you really need a pretty strong effect, so I don't think that data is 15 going to be available. 16 So I guess the que-- are there any other points on the prostate 17 cancer question that haven't, you know, been covered in one way 18 or another that anyone would like to see, and if not, I think we 19 should call this for a vote because we do want to make sure that 20 we have time to, as a Committee, draft the rationale for the breast 21 cancer inclusions before people have to leave, because every -- you 22 know, essentially everything -- you know, everything that's in this --23 we have to draft, as a Committee, everything that's going in this --24 in this letter to Dr. Howard. So are there any pressing issues 25 related to prostate cancer that have not already been covered? 26 **DR. TRASANDE:** This is Leo Trasande. I move to vote. 27 **DR. WARD:** Okay. Paul, go ahead with the vote. 28 **DR. MIDDENDORF:** Okay. Tom Aldrich? Oh, I need to restate the 29 motion. The motion is 'The Committee recommends adding 30 prostate to the list of covered conditions.' 31 DR. ALDRICH: I vote no. 32 **DR. MIDDENDORF:** Tom Aldrich, no. Steve Cassidy? 33 MR. CASSIDY: Yes. 34 **DR. MIDDENDORF:** Valerie Dabas?

MS. DABAS: Yes.

35

| 1  | DR. MIDDENDORF: John Dement?  |
|----|---|
| 2  | DR. DEMENT: No.   |
| 3  | DR. MIDDENDORF: Kimberly Flynn?                                     |
| 4  | MS. FLYNN: Yes.   |
| 5  | DR. MIDDENDORF: Bob Harrison?                                       |
| 6  | DR. HARRISON: No.   |
| 7  | DR. MIDDENDORF: Catherine Hughes?                                   |
| 8  | MS. HUGHES: Yes.  |
| 9  | DR. MIDDENDORF: Guille Mejia?                                       |
| 10 | MS. MEJIA: Yes.   |
| 11 | DR. MIDDENDORF: Julia Quint?  |
| 12 | DR. QUINT: Yes.   |
| 13 | DR. MIDDENDORF: Bill Rom?   |
| 14 | DR. ROM: No.  |
| 15 | DR. MIDDENDORF: Susan Sidel?  |
| 16 | MS. SIDEL: Yes.   |
| 17 | DR. MIDDENDORF: Glenn Talaska?                                      |
| 18 | DR. TALASKA: No.  |
| 19 | DR. MIDDENDORF: Leo Trasande?                                       |
| 20 | DR. TRASANDE: No.   |
| 21 | DR. MIDDENDORF: Liz Virginia Weaver?                                |
| 22 | DR. WEAVER: No.   |
| 23 | DR. MIDDENDORF: Liz Ward?   |
| 24 | DR. WARD: No.   |
| 25 | DR. MIDDENDORF: Okay, I have eight no and seven yes. The            |
| 26 | motion does not carry.  |
| 27 | Liz, I was wondering if we might want to take a very short break to |
| 28 | let people do whatever they need to for five minutes and then       |
| 29 | come back?  |
| 30 | DR. WARD: That's fine with me.                                      |
| 31 | UNIDENTIFIED: I actually object. I actually am going to have to get |
| 32 | off this call fairly soon, and I'm actually concerned about quorum  |
| 33 | UNIDENTIFIED: And I'm   |
| 34 | UNIDENTIFIED: (unintelligible) fifteen.                             |
| 35 | UNIDENTIFIED: going to be kicked out of my space at 5:00            |
|    |   |

1 o'clock. 2 DR. WARD: Okay, so let's --3 **DR. MIDDENDORF:** Let's proceed on then. 4 **UNIDENTIFIED:** Thank you very much. 5 **DR. WARD:** So we need a -- at least let's get the bullet points down for what the main reasons for which the Committee is 6 7 recommending that breast cancer be included are. 8 **DR. QUINT:** Well, I think one reason is the -- there are some 9 studies showing a positive relationship between levels of PCBs in 10 both sera and tissue, mammary tissue, and increased risk of breast 11 cancer. I can quote -- I mean I have -- I can get some -- you know, 12 it's not -- the studies are not consistent, but there are some 13 positive studies showing that relationship. 14 DR. WARD: Okay. And I think we should include, since I know that 15 there's a large volume of literature, I think it would be appropriate 16 to cite --17 **DR. MIDDENDORF:** Okay, I need to get that last thought down. 18 What is it, some studies correlating PCBs and what? 19 **DR. QUINT:** Breast cancer. 20 **DR. MIDDENDORF:** Breast cancer, okay. 21 **DR. QUINT:** Liz might be able to -- you're more familiar with the 22 data, but I do have -- I mean would you state that differently? 23 **DR. WARD:** I would guess I'd have to say: However, evidence is 24 conflicting. Because --25 **DR. QUINT:** (Indiscernible) 26 DR. WARD: -- (Indiscernible) some studies that don't find an 27 association. 28 **DR. TALASKA:** This is Glenn. There is some evidence of exposure 29 to PCBs in the World -- at Ground Zero and in the World Trade 30 Center. There was -- the window film showed it and there was also 31 -- some people were posi-- had higher -- there was PCBs in some 32 samples. 33 DR. QUINT: And then I think the lack of --34 **DR. MIDDENDORF:** What kinds of samples, Glenn? 35 DR. TALASKA: Biological samples. I don't remember what the --

| 1  | there were air samples window films, and there were some             |
|----|--|
| 2  | one or two congeners that were elevated in blood samples.            |
| 3  | DR. MIDDENDORF: Do I have this correct? 'Evidence of exposure        |
| 4  | to PCBs in air samples   |
| 5  | DR. TALASKA: Window films.   |
| 6  | DR. MIDDENDORF: films  |
| 7  | DR. TALASKA: And in some blood samples, and that would be let        |
| 8  | me try to find the   |
| 9  | DR. WARD: I think it maybe is the Dahlgren study.                    |
| 10 | DR. TALASKA: That's right, Dahlgren, thank you.                      |
| 11 | DR. WARD: And that's on page 17.                                     |
| 12 | DR. TALASKA: Yeah.   |
| 13 | DR. MIDDENDORF: Okay.  |
| 14 | DR. QUINT: Then I think we should also add the 2010 study            |
| 15 | showing that PCBs enhance the metastatic properties of breast        |
| 16 | cancer cells, activating the Rho-associated kinase, the ROCK, that   |
| 17 | was shown both in vivo and in vitro.                                 |
| 18 | DR. MIDDENDORF: Can you say that again for me, Julia?                |
| 19 | DR. QUINT: A recent a 2010 study showing that PCBs enhance           |
| 20 | the metastatic properties of breast cancer cells by activating the   |
| 21 | Rho-associated kinase, or R-O-C-K.                                   |
| 22 | DR. MIDDENDORF: You're going way too fast for me.                    |
| 23 | DR. QUINT: Oh, I'm sorry.  |
| 24 | DR. MIDDENDORF: Metastatic properties of breast                      |
| 25 | DR. QUINT: Cancer cells.   |
| 26 | DR. MIDDENDORF: Yes?   |
| 27 | <b>DR. QUINT:</b> By activating R-h-o associated kinase.             |
| 28 | <b>DR. MIDDENDORF</b> : R-h-o?                                       |
| 29 | DR. QUINT: Uh-huh.   |
| 30 | DR. MIDDENDORF: Okay.  |
| 31 | DR. QUINT: Dash, associated kinase, R-O-C-K. And that was shown      |
| 32 | in that study in vitro human breast cancer cells in vitro and also   |
| 33 | in vivo. And I don't know if you need this, but the cells were       |
| 34 | metastasized to bone, liver to bone, lung and liver.                 |
| 35 | DR. WARD: And Julia, if any of these studies is not available on the |

1 site, will you send them to Paul? 2 DR. QUINT: Yeah, I have this -- this study was a free download so I 3 can send the study, the one I just mentioned, and I will send -- I 4 will try -- I probably can get the one positive study, and I'll look for 5 the others showing the association between PCBs and breast 6 cancer risks. The one I'm looking at now is Cancer: 7 Epidemiological Biomarkers, 2000, by a Canadian group, Harrison, 8 et al. 9 DR. WARD: Now -- I mean I think there's at least 20 studies that 10 have been done. 11 DR. QUINT: That's right, and about 20 negative ones, as well. I 12 don't know, I'm just saying, I know it's inconsistent. 13 DR. WARD: Yeah. 14 **DR. QUINT:** I think it's the endocrine-disrupting properties of PCBs 15 as well. 16 **DR. WARD:** I was really --17 **DR. MIDDENDORF:** If you want something more, you need to give 18 me the words 'cause I don't want to put words in the Committee's 19 mouth. 20 **DR. QUINT:** Yeah, I -- let me find... 21 **DR. WARD:** Then we could probably say something like PCBs and 22 some other substances present at the WTC site --23 **DR. MIDDENDORF:** I'm sorry, say that again. 24 DR. WARD: And some other substances --25 DR. MIDDENDORF: Yes. DR. WARD: -- at the WTC site are --26 27 **DR. MIDDENDORF:** At the WTC site. 28 **DR. WARD:** -- are endocrine disrupters, therefore potentially could 29 (indiscernible). 30 DR. QUINT: And I think we should -- I don't know if you --31 **DR. TALASKA:** Liz, it's Glenn. I have to ring off. 32 DR. WARD: Okay. Thanks, Glenn. 33 **DR. TALASKA:** Sure thing, bye-bye. 34 DR. WARD: And Julia, I think it probably should say some -- well, I 35 don't know if all PCB congeners are endocrine disrupters. I --

1 **DR. QUINT:** Right. 2 **DR. WARD:** -- think that some of them are estrogenic and some of 3 them are anti-estrogenic. 4 **DR. QUINT:** That's exactly right, so we'd have to -- I don't have 5 that in front of me, unfortunately. So maybe just saying -- the ones that were linked to the breast cancer risk in this one study were 6 7 congeners 105 and 108 -- I'm sorry, 105 and 118, and 170 and 180. 8 DR. WARD: My suggestion would be not to include -- get to that 9 level of specificity --10 **DR. QUINT:** Yes, right. 11 **DR. WARD:** -- because we're not going to have time to look at 12 other studies and --13 DR. QUINT: Okav. 14 **DR. WARD:** -- (indiscernible) same thing. 15 **DR. QUINT:** Exactly. 16 **DR. WARD:** So with the sentence that you're typing, Paul, it could 17 be -- you could just -- '...endocrine disrupters, which potentially 18 could influence breast cancer risk.' And we could -- somewhere get 19 in there, 'Breast cancers are highly dependent on hormonal factors 20 and therefore endo... 21 DR. MIDDENDORF: On hormonal --22 **DR. WARD:** Factors, or are highly related to hormonal factors, 23 therefore -- yeah. Therefore could be impacted by endocrine --24 further to endocrine disrupters. 25 Then I think our next point could be that there's varying -- you 26 know, that the opportunities to identify (indiscernible) related to 27 occupational exposures --28 **DR. MIDDENDORF:** To identify what related to occupational 29 exposures? 30 **DR. QUINT:** Increased breast cancer risks. 31 DR. WARD: Yeah. 32 **UNIDENTIFIED:** It's not showing up on the screen -- on the 33 computer screen. 34 **DR. MIDDENDORF:** Can you see it now? 35 DR. QUINT: Yes.

| 1  | DR. MIDDENDORF: Okay.  |
|----|--|
| 2  | DR. QUINT: To identify breast cancer risks, right?                 |
| 3  | DR. WARD: Right, related to occupational exposures have been       |
| 4  | extremely limited due to small numbers of women in industrial      |
| 5  | occupations.   |
| 6  | DR. MIDDENDORF: Small numbers of women                             |
| 7  | DR. WARD: In industrial occupations and/or yeah, in                |
| 8  | epidemiologic studies of industrial populations.                   |
| 9  | DR. MIDDENDORF: You'll have to restate that small numbers of       |
| 10 | women in   |
| 11 | DR. QUINT: Included.   |
| 12 | DR. WARD: It's due to small numbers of women in industrial         |
| 13 | population studies.  |
| 14 | DR. MIDDENDORF: Industrial population studies?                     |
| 15 | DR. WARD: Yeah, that's good.                                       |
| 16 | DR. MIDDENDORF: Okay.  |
| 17 | DR. WARD: Okay. Are there any other points in the rationale that   |
| 18 | we should include?   |
| 19 | MS. SIDEL: Hi, it's Susan Sidel. Do we want to say anything about  |
| 20 | the lack of studies on women in this program generally?            |
| 21 | DR. WARD: Not sure that's a part of the scientific rationale for   |
| 22 | recommending   |
| 23 | MS. SIDEL: Okay, you're right.                                     |
| 24 | DR. WARD: be included.   |
| 25 | MS. SIDEL: Okay.   |
| 26 | DR. WARD: Okay, are there any more points on that, or Paul can     |
| 27 | take I think Paul can take the language that he's got and and      |
| 28 | references sent by Julia and finalize the rationale for            |
| 29 | MS. FLYNN: This is Kimberly. Are you interested in the citation on |
| 30 | shift work, or is that not useful?                                 |
| 31 | DR. WARD: I think we could add that as an additional bullet        |
| 32 | MS. FLYNN: Okay.   |
| 33 | DR. WARD: included in the COPC list of potentially of potential    |
| 34 | contamin while not included in the list of potential               |
| 35 | contaminants of concern, it is known that, you know, shift work    |

1 was done at the World Trade Center site and IARC has found -- I 2 can't remember if it's 'limited' or 'sufficient' evidence for increased 3 risk of breast cancers associated with shift work involving -- I think 4 it's involving -- I forget, but I'll see if I can find it, but I think that 5 would probably be enough for the Committee to agree on. So Paul, are you getting that? 6 7 DR. MIDDENDORF: No, my mind was elsewhere, I'm sorry. Do you 8 have another bullet, and what is the bullet? 9 DR. WARD: IARC has found -- then leave a blank for 'limited' or 10 'sufficient' 'cause I can't remember which, whichever one is correct 11 -- evidence for an association between breast cancer and shift 12 work. There was a little modifier of the shift work, but I think --13 **DR. MIDDENDORF:** Wait a minute, you're getting too far ahead of 14 me. 15 DR. WARD: Between breast --16 **DR. MIDDENDORF:** Between breast cancer and shift work -- okay. 17 DR. WARD: Then, period. It -- you know, both -- both -- I'm trying 18 to think -- both shift work and shifts of long duration were common 19 at the World Trade Center site. Yeah, were common at the World 20 Trade -- among personnel at the World Trade Center. 21 **DR. MIDDENDORF:** I'm sorry, what? 22 **DR. WARD:** Were -- among personnel involved in World Trade 23 Center rescue, recovery -- the list of -- list of categories of people 24 that were involved in the cleanup, the recovery, the rescue, the -- I 25 think Guille gave me that language for the first part. Right, Guille, 26 do you remember? Still here? Okay. 27 **DR. ALDRICH:** Do you want to know about a typo on the previous 28 page? Line 31, metastatic. 29 **DR. MIDDENDORF:** Such things are going to be able to be handled 30 by Liz. She can do copy editing after this. It's just that the content 31 has to be finished here in this meeting. 32 **UNIDENTIFIED:** Okay, I have what I think are pretty... 33 **DR. MIDDENDORF:** This is not finished -- both shift work and shifts 34 of long duration were common --35 **DR. WARD:** Okay, so I'm looking for the --

1 DR. ALDRICH: -- at the World Trade Center. 2 DR. WARD: At the -- yeah, that's good enough, I think, for this. I 3 mean I just found the list of -- you know, the language that Guille 4 Mejia suggested was 'engaged in rescue, recovery, demolition 5 debris cleanup, and other related services.' **DR. ALDRICH:** Well, why be so specific? 6 7 **DR. WARD:** Yeah, we don't have to be that -- yeah. 8 **UNIDENTIFIED:** (Unintelligible) volunteers. 9 DR. WARD: Is everybody comfortable with the language as Paul 10 has it typed now? 11 **UNIDENTIFIED:** Will you also be sending the Committee members a 12 revision of this draft with the changes? What's the time frame for 13 that? 14 **DR. MIDDENDORF:** When this meeting is over I'm going to save it. 15 I will send it to the entire Committee. The Committee needs to 16 commission Liz to make typographical and copy editing changes to 17 whatever is here, but nothing more. 18 **UNIDENTIFIED:** Thank you very much. 19 **DR. MIDDENDORF:** Okay. There are some things here in the report 20 that I think need to be edited out. 21 **DR. QUINT:** Not to mention the things that are not factually 22 correct. 23 **DR. MIDDENDORF:** Well, on that problem we've got this note on, the text highlighted below does not reflect, and we don't want 24 25 that. 26 **DR. QUINT:** I'm sorry? 27 **DR. ALDRICH:** (Unintelligible) 28 **DR. MIDDENDORF:** I'm sorry, on page three at the very top it says 29 (reading) Please note that the text highlighted below does not 30 reflect the final recommendation of the STAC. The text is for 31 review by the Committee. We still take discussion of options for 32 the recommendation and will be used as appropriate in the final 33 draft to support the recommendations. 34 So I'm assuming that you want that out. DR. ALDRICH: Yes. 35

1 **DR. MIDDENDORF:** Is that correct? 2 DR. WARD: Yes. 3 **DR. QUINT:** Right. 4 DR. MIDDENDORF: All right. Option one was voted down. Do you 5 want that out? DR. WARD: Yes. 6 7 DR. QUINT: Yes. 8 **DR. MIDDENDORF:** So all of option one goes away. 9 **DR. ALDRICH:** Although at some point later on there was some 10 reference to some members of the Committee supported more and 11 -- no reason not to leave that in. Right? 12 UNIDENTIFIED: Yeah, I have to -- you know what, I wanted to 13 comment on the option one because it raised like limitations of 14 data and stuff like that, which is relevant. Like if you do a scientific 15 experiment you talk -- have a limitations section, so some of it is 16 relevant to the discussion, particularly when you talk about, you 17 know, some of the evidence and -- you know, by -- you look at --18 you can't delete all of option one. 19 **DR. MIDDENDORF:** Then you're going to need to go line by line 20 and tell me what to delete and what not to delete, or what to 21 change. 22 DR. WARD: So Paul --23 **DR. MIDDENDORF:** Yes. 24 **DR. WARD:** -- I think for sure you want to keep the last paragraph 25 in option one. Maybe we'll want to move it to the end. 26 **UNIDENTIFIED:** Perfect. 27 **UNIDENTIFIED:** I agree, that's really good. 28 **UNIDENTIFIED:** And what about the second to last paragraph 29 about the findings of the FDNY study? So that's on page four, lines 30 4, 5 and 6. That should also be included. 31 **DR. ALDRICH:** I think that's discussed elsewhere and it doesn't 32 advance this argument. 33 **UNIDENTIFIED:** Okay. 34 DR. WARD: Yeah. 35 **DR. MIDDENDORF:** Okay, I'm -- I need you to tell me exactly what

1 to do. 2 **DR. WARD:** Okay, take that paragraph and then scroll to the --3 **DR. MIDDENDORF:** This paragraph, 'In addition to the evidence...'? 4 DR. WARD: Yes. Scroll on down to the end of the letter to Dr. 5 Howard. DR. MIDDENDORF: Go ahead. Scroll down? 6 7 DR. WARD: Yeah. 8 **DR. ALDRICH:** Page 28, more or less. 9 DR. WARD: Okay. So go back -- okay. So the question -- so maybe we move it right before the 'We appreciate the opportunity...' 10 11 paragraph, and we need to figure out some way to make the 12 transition. 13 **DR. MIDDENDORF:** So you want this paragraph removed from 14 here. 15 DR. WARD: Yes. 16 **DR. MIDDENDORF:** You want it at this insertion point. 17 **DR. WARD:** I think so. So we just need to modify that first 18 sentence so it's a more appropriate transition. Maybe something 19 like: The Committee recognizes the limitations of existing evidence 20 and the possibility that the presence of multiple exposures and 21 mixtures could produce unexpected results. Something like that. 22 **DR. ALDRICH:** Well, it has to be something specifically related to 23 the non-covered cancers. 24 DR. WARD: I think it's really the issue of acknowledging that 25 they're -- we're making this recommendation in the light of 26 considerable data limitations and uncertainties because --27 DR. ALDRICH: The previous paragraph exactly leads into this. If 28 this was -- rather than a new paragraph, part of the previous 29 paragraph. 30 **DR. WARD:** What are you seeing as the previous paragraph? 31 DR. ALDRICH: (Reading) The Committee also recommends that, in 32 addition to treatment of the listed cancers -- for the listed cancer 33 sites, the health program provides funding and guidelines for 34 medical screening and early detection based on a review of 35 evidence regarding risks and benefits to the --

| 1  | Oh, no, you're right, it doesn't it doesn't (unintelligible).         |
|----|---|
| 2  | DR. WARD: And actually at the end of the paragraph we make            |
| 3  | reference to the lack of epidemiologic data on female breast          |
| 4  | cancer, so we probably need to take that sentence out now that        |
| 5  | we've included breast.  |
| 6  | UNIDENTIFIED: Right.  |
| 7  | <b>DR. WARD:</b> So we need to take the last two sentences here out.  |
| 8  | DR. MIDDENDORF: These two sentences?                                  |
| 9  | DR. WARD: Yes.  |
| 10 | DR. MIDDENDORF: Additional concern starting with 'An                  |
| 11 | additional concern' on line 14 and ending with 'reproductive organs   |
| 12 | is limited' on line 18?   |
| 13 | DR. WARD: Right.  |
| 14 | DR. ALDRICH: You can leave that second to last sentence there.        |
| 15 | That's not contradicts anything we've said before, and it's           |
| 16 | relevant.   |
| 17 | DR. WARD: Okay, so it's just the last one on breast.                  |
| 18 | DR. ALDRICH: Yeah.  |
| 19 | DR. MIDDENDORF: So starting on line 16 with '(indiscernible)          |
| 20 | availability' and going through 'is limited.'                         |
| 21 | DR. WARD: Right.  |
| 22 | DR. MIDDENDORF: On line 18. Okay.                                     |
| 23 | DR. ALDRICH: How about instead of at the beginning of that, the       |
| 24 | second line of that paragraph, instead of saying 'arguments in favor  |
| 25 | of listing all cancers', 'arguments in favor of listing additional    |
| 26 | cancers'?   |
| 27 | <b>DR. WARD:</b> Okay. But then we need to have a final sentence that |
| 28 | explains why we didn't, I guess. We could at the end say:             |
| 29 | However, the majority of the Committee felt that                      |
| 30 | <b>DR. ALDRICH:</b> Yeah, you're right.                               |
| 31 | DR. WARD: you know, the recommendations that were made                |
| 32 | reflected the best available or kind of sound scientific rationale    |
| 33 | and reflected the best available evidence at this time.               |
| 34 | DR. ALDRICH: I like it.   |
| 35 | DR. MIDDENDORF: What is it where and what?                            |

| DR. WARD: At the end of that paragraph                             |
|--|
| DR. MIDDENDORF: Yes.   |
| DR. WARD: However, the majority of Committee members               |
| agreed that the recommendations made above have are based          |
| on a sensible scientific rationale and reflect the best            |
| DR. MIDDENDORF: Sorry, say that again.                             |
| DR. WARD: A sensible scien are based on a sound scientific         |
| rationale and the best and the best evidence available today.      |
| DR. ALDRICH: That's good.  |
| DR. WARD: Okay. Looks good to me.                                  |
| DR. ALDRICH: Like it a lot.  |
| DR. WARD: Good. So shall we move on to the                         |
| DR. MIDDENDORF: How about if we go back up and look at option      |
| one. Does the rest of this go away?                                |
| DR. WARD: I think so.  |
| DR. ALDRICH: Yep.  |
| DR. MIDDENDORF: And with highlighted. You want this header,        |
| option two?  |
| DR. WARD: No, that can go away, I think.                           |
| DR. MIDDENDORF: (Indiscernible) trying to do.                      |
| DR. WARD: Endnotes is horrible. Endnotes will hijack your          |
| document.  |
| DR. MIDDENDORF: And she hung up.                                   |
| DR. WARD: All right. Do you have a hard copy that you can write    |
| notes on?  |
| (Pause)  |
| DR. MIDDENDORF: Okay, back to doing business. Okay, so this        |
| at least I thought I was.  |
| (Pause)  |
| DR. MIDDENDORF: It'll pull up other documents but this one is      |
| hung up.   |
| DR. WARD: Yeah, I mean and I do think you're at the point where    |
| maybe a hard copy would suffice 'cause I think all we're going to  |
| I mean I think all we need to do here is cross out the bold header |
| and then   |
|  |

1 **DR. MIDDENDORF:** If you want to do that -- I mean you can work 2 on that yourself. 3 DR. WARD: Well, I can't do it and share it with the Committee, so 4 what I'm saying is we cross out the bold header, then instead of 5 saying -- I would suggest amending -- the next sentence is 'The Committee recommends listing of the following site groupings and 6 7 sites' -- and then we take out 'each to be discussed and voted on 8 separately' -- 'be listed as World Trade Center-related conditions, 9 based on the strength of the evidence summarized in Table 4 and 10 additional evidence discussed below.' And that's, I think, all you need to do. 11 12 **DR. MIDDENDORF:** Okay. Is that what the Committee wants? 13 DR. ALDRICH: I'm for it. 14 DR. WARD: That's fine. 15 **UNIDENTIFIED:** Sounds good to me. 16 **DR. MIDDENDORF:** I obviously can't do anything more with this 17 document, so --18 **DR. ALDRICH:** Well, I think the Commit-- this is Tom Aldrich. I 19 think the Committee -- the sense of the Committee is -- we know 20 what needs to be accomplished and we trust Liz to do it. 21 **DR. WEAVER:** This is Virginia. I agree. 22 MS. MEJIA: I agree, too. This is Guille. 23 **DR. TRASANDE:** This is Leo Trasande. I agree, and I also have to 24 sign off at this point. 25 **DR. DEMENT:** This is John Dement, and I agree as well. 26 DR. QUINT: I agree -- Julia. 27 **DR. HARRISON:** This is Bob, I agree. 28 **UNIDENTIFIED:** (Unintelligible), I agree. 29 MS. FLYNN: This is Kimberly. I agree, but I have one question, 30 which is any -- any small wording changes, are they still possible or 31 not? I'm thinking of, for instance, adding the word 'survivors' to 32 line 28. Possible? 33 MR. CASSIDY: This is -- in the interim -- this is Steve Cassidy. I 34 agree. 35 **DR. WARD:** Can you read that full sentence just to make sure we

| 1  | got it in the right place?  |
|----|---|
| 2  | MS. FLYNN: Are you asking me, Liz?                                  |
| 3  | DR. WARD: Yes, because I think I'm not sure what line 28 is         |
| 4  | anymore.  |
| 5  | MS. FLYNN: Oh, I'm sorry, I understand. (reading) However, the      |
| 6  | Committee considers that the high prevalence of acute symptoms      |
| 7  | and chronic conditions observed in large numbers of rescue,         |
| 8  | recovery, cleanup and restoration workers It should say 'and        |
| 9  | survivors' (reading)as well as qualitative descriptions of          |
| 10 | exposure conditions in downtown Manhattan et cetera.                |
| 11 | DR. WARD: Okay, so is everybody on the Committee happy with         |
| 12 | that change?  |
| 13 | UNIDENTIFIED: That's fine.  |
| 14 | UNIDENTIFIED: Fine.   |
| 15 | UNIDENTIFIED: (Unintelligible) it's good.                           |
| 16 | UNIDENTIFIED: Right.  |
| 17 | MS. FLYNN: And I don't know how much patience people have for       |
| 18 | anything additional like that.                                      |
| 19 | DR. WARD: And Julia, can you send me I assume these factual         |
| 20 | errors are not something that the Committee needs to                |
| 21 | (unintelligible) the group to be addressed, so if you'd just let me |
| 22 | know what they are.   |
| 23 | DR. MIDDENDORF: If there are substantive changes, then the          |
| 24 | Committee needs to be aware of them and agree to them.              |
| 25 | DR. WARD: Okay, Julia, can you kind of go through them quickly      |
| 26 | with I mean we won't need to make them in the document, but         |
| 27 | we can  |
| 28 | DR. WEAVER: This is Virginia and I need to sign off. I'm sorry.     |
| 29 | DR. WARD: Okay, thanks for coming.                                  |
| 30 | (Pause)   |
| 31 | DR. WARD: Julia? Hello?   |
| 32 | MS. DABAS: Hi, it's Valerie. Do we still have a quorum?             |
| 33 | DR. MIDDENDORF: That's a good question.                             |
| 34 | UNIDENTIFIED: I'm here right now, but they're kicking us out. It's  |
| 35 | almost 5:30, so you need me to vote on something?                   |
|    |   |

| 1  | DR. WARD: Well, I guess at this point Paul, I don't know that we       |
|----|--|
| 2  | have any choice but to   |
| 3  | DR. MIDDENDORF: I think we're likely below quorum at this point.       |
| 4  | DR. WARD: Yeah, so we'll so Julia, if you're still on, can you send    |
| 5  | me a list of the factual changes or send it to the entire              |
| 6  | Committee, and I will go ahead and do fact-checking and                |
| 7  | incorporate them?  |
| 8  | DR. MIDDENDORF: And whatever that is, we'll probably need to           |
| 9  | post that so that everyone can see, it's part of the open record.      |
| 10 | DR. WARD: Okay, Paul, it may be down to just you and I.                |
| 11 | DR. DEMENT: No, I'm this is John. I'm here, but I don't think we       |
| 12 | have enough to do anything.  |
| 13 | DR. WARD: Yeah.  |
| 14 | DR. ALDRICH: Tom Aldrich, I'm also here, but you know, it's            |
| 15 | we're pretty much done and I think you can handle the additional       |
| 16 | facts and changes and what-not.  |
| 17 | DR. QUINT: Liz?  |
| 18 | DR. WARD: Yes.   |
| 19 | DR. QUINT: I'm sorry, my phone gave out so I was off for a minute.     |
| 20 | DR. WARD: Oh, okay.  |
| 21 | DR. MIDDENDORF: I think we're below the quorum.                        |
| 22 | DR. QUINT: Okay, 'cause I had some er there's some a couple            |
| 23 | of errors on page 15   |
| 24 | DR. WARD: Okay.  |
| 25 | <b>DR. QUINT:</b> that I wanted to call to your attention, but I guess |
| 26 | it's too late now.   |
| 27 | DR. WARD: Well, not necessarily. I think the Committee basically       |
| 28 | agreed that you know, that we can make those corrections               |
| 29 | DR. QUINT: Okay.   |
| 30 | DR. WARD: so we would like you to put them in a list so that           |
| 31 | they can be shared   |
| 32 | DR. QUINT: Okay, that's fine.  |
| 33 | MS. HUGHES: I second it. Catherine Hughes seconds it.                  |
| 34 | DR. MIDDENDORF: I don't know that we have a quorum that could          |
| 35 | even vote on it, so  |

| 1  | DR. WARD: (Unintelligible) I don't know.                            |
|----|---|
| 2  | DR. QUINT: Yeah, my phone just completely went off. All right, I'll |
| 3  | send you those.   |
| 4  | DR. WARD: Thank you.  |
| 5  | DR. MIDDENDORF: Send it to everyone, please.                        |
| 6  | DR. QUINT: I'm sorry?   |
| 7  | <b>DR. MIDDENDORF:</b> Send it to everyone.                         |
| 8  | DR. QUINT: Oh.  |
| 9  | UNIDENTIFIED: Liz, I have to check off also. I want to thank you    |
| 10 | and Paul for doing this, and we'll be in touch. Thank you.          |
| 11 | DR. WARD: Great, thank you.   |
| 12 | UNIDENTIFIED: I have to sign off, too. Thank you so much, Paul      |
| 13 | and Liz and everybody else on the Committee. Thank you very         |
| 14 | much.   |
| 15 | DR. WARD: Thank you.  |
| 16 | DR. MIDDENDORF: Yeah, we need to cut this off then. Thanks to       |
| 17 | everyone on the Committee. On behalf of the program I want to       |
| 18 | express a lot of appreciation for all the hard work under very      |
| 19 | strenuous conditions and think you've done an excellent job.        |
| 20 | Thank you very much.  |
| 21 | UNIDENTIFIED: Thank you, Paul. Thank you, Liz.                      |
| 22 | UNIDENTIFIED: And thank you, Liz. Thank you so much. See you        |
| 23 | later, bye.   |
| 24 | (Teleconference concluded at 5:32 p.m.)                             |
| 25 |   |
| 26 |   |
| 27 |   |

## CERTIFICATE OF COURT REPORTER STATE OF GEORGIA COUNTY OF FULTON

I, Steven Ray Green, Certified Merit Master Court Reporter, do hereby certify that I reported the above and foregoing on the day of March 28, 2012; and it is a true and accurate transcript of the proceedings captioned herein.

I further certify that I am neither related to nor counsel to any of the parties herein, nor have any interest in the cause named herein

WITNESS my hand and official seal this the 26th day of April, 2012.

STEVEN RAY GREEN, CCR, CVR-CM-M, PNSC CERTIFIED MERIT MASTER COURT REPORTER

CERTIFICATE NUMBER: A-2102